

An Intervention to Involve Family in Decisions about Life Support

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Dedicated to my family:

Marko, Kalyna, Maksym, Jakob and Hannah

Dissertation Abstract

Purpose. To systematically develop and field test an intervention to engage families and healthcare teams in the decision-making process about life support for critically ill patients in the Intensive Care Unit (ICU).

Setting. Adult medical-surgical ICU at a Canadian academic teaching hospital.

Methods. The International Patient Decision Aid Standards (IPDAS) criteria and the Interprofessional Shared Decision Making (SDM) model guided the study of families facing decisions about life support for their relative in ICU that involved: 1) systematic review; 2) qualitative descriptive study; 3) mixed methods field test of a novel patient decision aid (DA).

Systematic review findings. Of 3162 citations, four trials evaluated interventions to improve communication between health professionals and patients/families. One intervention met eight of nine criteria for SDM but did not evaluate its effect on the benefit to communication.

Qualitative study findings. Six family members and nine health professionals identified two options (life support or comfort care) and values associated with these options. Values included maintaining quality of life, surviving critical illness, minimizing pain and suffering, not being attached to machines, giving the family enough time to adapt emotionally to the patient's health situation, and the judicious use of healthcare resources. Families were unlikely to become engaged without healthcare professionals making the decision explicit and minimizing other barriers across the decision-making process.

Field test findings. Family members and health professionals for eight patients indicated that the DA was feasible to use, acceptable to users, had the potential to do what was intended, and did not seem to present adverse consequences to users. An enhanced delivery strategy is needed for future evaluation of its effect on facilitating patient/family involvement in decisions.

Conclusions. Limited involvement of families in the process of decision-making about life support in the ICU reinforced the need for effective interventions to facilitate SDM. These studies validated the operationalization of the IPDAS criteria, as part of a systematic process for developing and field testing DAs. However, IPDAS criteria stop short of elements necessary to consider when implementing the DA in the processes of care.

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Table of Contents

Dissertation Abstract.....	iii
Acknowledgements.....	v
Abbreviations.....	xiii
Chapter 1: Introduction and Organization of the Dissertation	1
Problem Statement.....	1
Background.....	2
Guiding Conceptual Models.....	8
The Interprofessional Shared Decision Making (IP-SDM) model.....	8
The International Patient Decision Aid Standards (IPDAS) Criteria.....	11
Reference List.....	15
Chapter 2: Interventions for Shared Decision-Making about Life Support in the Intensive Care Unit: A Systematic Review.....	28
Abstract.....	28
Introduction.....	30
Review Objectives.....	32
Methods.....	32
Results	35
Decision Quality.....	43
Shared Decision Making Process.....	43
Patient Mortality.....	44
Family Member Health Status	44
Resource Use.....	44
Discussion.....	45
Elements of Shared Decision Making in Interventions.....	46
Evidence of the Shared Decision Making Process.....	48
Downstream Effects of Shared Decision Making.....	49
Limitations	51
Implications for Clinical Practice.....	51
Implications for Research	53
Conclusion.....	53
Financial Support.....	54

Contributions of Team Members.....	54
Acknowledgements	54
Reference List.....	55
Chapter 3: Family Involvement in the Process of Decision-Making about Life Support in the Intensive Care Unit: A Qualitative Study	65
Abstract.....	65
Introduction	66
Methods	68
Results	70
How do professionals and families conceptualize the options?	70
What values associated with options underpin the participants' preference?	71
What roles did participants have in the decision-making process?.....	73
What were the barriers to involving families in SDM?.....	74
Discussion.....	76
A key barrier to involving family is 'not presenting alternative options'	77
Patient centered care requires that patient values influence decisions	77
SDM calls for a renewed focus on deliberation	78
IP-SDM model can be used to identify modifiable barriers.....	79
Study strengths and limitations	80
Implications and conclusions.....	82
Reference list	87
Chapter 4: Field Testing a Patient Decision Aid to Engage Families in Decision Making about Life Support in the Intensive Care Unit.....	94
Abstract.....	94
Background.....	96
Methods	98
Participants and Setting.....	98
The Patient Decision Aid Intervention.....	98
Procedure	99
Outcomes	100
Data Analysis	102
Results	103
Feasibility: Patient Decision Aid Use	104

Feasibility: Use During Family Meeting.....	105
Acceptability	105
Balance.....	106
Understandability	106
Potential to Have Desired Impact Without Adverse Consequences	106
Discussion.....	107
IPDAS Criteria for Field Testing	108
Family Member Distress.....	111
Suggested Criteria for Field Testing	112
Limitations	112
Conclusions	113
Competing Interests.....	114
Author’s Contributions	114
Acknowledgments and Funding	114
Reference List.....	130
Chapter 5: Integrated Discussion	136
Systematic Decision Aid Development using IPDAS Criteria.....	136
Validating the IP-SDM Model in the ICU Setting	146
Roles of Stakeholders.....	146
Decision	147
Information Exchange.....	148
Values and Preferences	148
Preferred Choice.....	150
Actual Choice.....	151
Environment.....	152
Implications for Nursing.....	153
Practice.....	153
Education	155
Future Research.....	156
Conclusion.....	159
Reference List.....	161
Chapter 6: Contribution of Collaborators	169
Appendices.....	172

Appendix A Qualitative Interview Guide 173
Appendix B Decision Aid for Families 175
Appendix C Decision Summary Report 183
Appendix D Decision Aid Development 184
Appendix E Consent Forms 192
Appendix F Decision Coaching 202
Appendix G Field Testing Questionnaires 208

List of Tables

Table 1.1 International Patient Decision Aids Standards (IPDAS) Criteria	12
Table 1.2 Relationship of Dissertation Content to Systematic Development Process.....	14
Table 2.1 Criteria for Study Inclusion	33
Table 2.2 Excluded Intervention Studies	37
Table 2.3 Characteristics of Included Studies.....	38
Table 2.4 Elements of Shared Decision Making in Interventions	41
Table 2.5 Quality Appraisal	42
Table 3.1 Characteristics of participants.....	84
Table 3.2 Barriers to SDM in ICU	85
Table 4.1 Field testing methods	116
Table 4.2 Characteristics of enrolled participants.....	121
Table 4.3 Use to prepare for family meetings.....	122
Table 4.4 Use during family meetings	123
Table 4.5 Acceptability	125
Table 4.6 Potential to have desired impact	126
Table 4.7 Potential influence on family member psychological distress.....	128
Table 4.8 Suggested criteria for field testing decision aids	129
Table 5.1 Implication for Theory and Nursing	137
Table 5.2 Study Objectives and Summary of Findings	138
Table 5.3 Barriers remaining after the DA intervention	140
Table 6.1 Contribution of Collaborators	171
Table C.1 Components of intervention addressing identified barriers to involving families	186
Table C.2 IPDAS Checklist	190
Table D.1 Characteristics of Decision Coaching	204

List of Figures

Figure 1.1 The Interprofessional Shared Decision Making (IP-SDM) Model..... 9

Figure 2.1 MEDLINE Search Strategy 34

Figure 2.2 Flow of Information through the Systematic Review Process 36

Figure 3.1 The Interprofessional Shared Decision Making (IP-SDM) Model..... 83

Figure 4.1 Field testing flowchart..... 115

Abbreviations

AMED	Allied and Complementary Medicine Database
CARENET	Canadian Researchers at End-of-life Network
CENTRAL	The Cochrane Central Register of Controlled Trials
CI	Confidence interval
CINAHL	The Cumulative Index to Nursing and Allied Health Literature
CIT	Critical Incident Technique
DA	Patient Decision Aid
EMBASE	The Excerpta Medica Database
ICU	Intensive Care Unit
IPDAS	International Patient Decision Aid Standards
IP-SDM	Interprofessional Shared Decision Making
IQR	Inter quartile range
K2A	Knowledge-to-action
MEDLINE	Ovid MEDLINE, National Library of Medicine
PRISMA	Preferred Reporting Items for Systematic Review and Meta-Analysis
RC	Research Coordinator
RCT	Randomized Controlled Trial
RN	Registered Nurse
SD	Standard Deviation
SDM	Shared Decision Making
SUPPORT	The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments
TOH	The Ottawa Hospital
TPB	Theory of Planned Behavior
US	United States

Chapter 1: Introduction and Organization of the Dissertation

The purpose of the dissertation was to apply the systematic process recommended by the International Patient Decision Aid Standards (IPDAS) collaboration (Elwyn et al., 2006) to develop and field test a patient decision aid to enhance family preparation to engage with healthcare professionals in the decision about life support for their relative in the Intensive Care Unit. This first chapter orients the reader to the three studies that constitute the dissertation research. More specifically, I describe the problem from clinical practice. Then, I provide more detail about the background issues that influence the clinical problem by highlighting the available literature. Finally, I describe the guiding conceptual models to clarify the organization of the dissertation.

Problem Statement

The health decision-making process involves engaging patients who bring expertise about their biography of illness and personal values as partners in their care (Department of Health: The Expert Patient Task Force, 2001). Patients of all ages experience both health and illness in the context of their lives with family, which they define by their biological, legal, or emotional relationships (Wright & Leahey, 2009). Since patients who depend most on the healthcare system may also rely heavily on their families, a patient and family-centered approach to the health decision-making process is needed to ensure safe and effective health care delivery (Conway et al., 2006; Johnson, 2000). When the health decision-making process does not engage patients and their families, the care provided does not necessarily match patient preferences or meet their needs (Alpert & Emanuel, 1998; Danis, Gerrity, Southerland, & Patrick, 1988; Danis et al., 1996; Danis, 1998). This is particularly evident in critical care settings, such as the Intensive Care Unit (ICU), where patients' voices are often silenced by interventions such as mechanical ventilation and sedation. Consequently family members of ICU patients may be asked to share their insights about the values and preferences of their family member, particularly around decisions about life support.

Inadequate communication with families during the process of decision-making about life support is a problem in ICU. For example, while many family members wanted to be involved in this decision (Heyland, Tranmer, O'Callaghan, & Gafni, 2003; Heyland et al., 2006), this often did not occur (Boyle, Miller, & Forbes-Thompson, 2005; Azoulay & Sprung, 2004; Azoulay & Pochard, 2003; Curtis et al., 2005; Jamerson et al., 1996; Kirchoff et al., 2002; Levy & McBride, 2006). Therefore, improved communication with families about the use of life support at the end-of-life in the ICU is needed in order to ensure that the care provided in the ICU settings is respectful of and responsive to the values and preferences of an individual patient.

Background

In the ICU, decisions about whether to use life support or to withhold or withdraw life support are made for critically ill patients who are often too ill to engage in the decision-making process. These decisions might be made by family members with the patient's interprofessional healthcare team which includes physicians, nurses, respiratory therapists, social workers, and pastoral care workers. The decision arises when a patient is admitted to ICU with life support that was started during a crisis or when a patient's health declines to the extent that life support interventions are considered as an option. Of those patients who die in ICU, a decision to withhold or withdraw of life support is made prior to 50% to 90% of those deaths (Keenan et al., 1997; Prendergast & Luce, 1997; Ferrand, Robert, Ingrand, & Lemaire, 2001; Hall & Rocker, 2000). Withholding refers to not using some life support modalities (such as medications that support the heart, mechanical ventilation, oxygen, dialysis) whereas withdrawal means providing comfort care and sedation while discontinuing life support (Keenan et al., 1997). Interestingly, researchers have shown that there is considerable practice variation in the care provided at the end-of-life. Despite a legal requirement that patients or their substitute decision-maker provide consent for life support treatment, there is less clarity about the need to provide consent for withdrawal and there is evidence that conflict occurs between the healthcare team and families (Abbott, Sago, Breen, Abernethy, & Tulsy, 2001; Swigart, Lidz, Butterworth, & Arnold, 1996; Tilden, Tolle, Nelson, Thompson, & Eggman, 1999). Further, consent for treatment is not always obtained and healthcare professionals seem

to base their decisions on factors other than patient/family wishes or values (Ferrand et al., 2001; Garland, Connors, Garland, & Connors, 2007; Guyatt et al., 2003; Johnson & Kramer, 2000; Larochelle, Rodriguez, Arnold, & Barnato, 2009; Schneiderman, Kaplan, Pearlman, & Teetzel, 1993; Schneiderman, Kaplan, Rosenberg, & Teetzel, 1997; Somogyi-Zalud, Zhong, Hamel, & Lynn, 2002). Taken together, these issues reflect a state of poor communication with patients and families during the decision-making process. Issues surrounding practice variation, legal structures, conflict with families are described in greater detail here, using the available literature to describe the problem and a potential solution more clearly.

There is considerable practice variation in the care provided at the end-of-life. This may occur because similar to other decisions where there is evident practice variation, the decision about whether or not to use life support is a high stakes decision where there is more than one reasonable option, each with benefits and harms that people value differently, and without clear advantage in terms of health outcomes. The Dartmouth Atlas Project demonstrated that costly high intensity and high intervention care, like the use of life support in the ICU, is associated with no better quality of care and possibly results in worse health outcomes at the end-of-life (Wennberg et al., 2006). There is wide variation in the intensity of care provided at the end-of-life that is not explained by the burden of illness but may rather be associated with the availability of services or other factors (Fisher et al., 2000; Wennberg et al., 2004; Wennberg, Fisher, Goodman, & Skinner, 2008; Canadian Institute for Health Information, 2007; Menec et al., 2004). These findings suggest that some re-examination of the healthcare system is needed to ensure that the right care is provided in the right setting. Unfortunately, population level data about variations does not tell us whether too much care, too little care, or the wrong care is being provided to individuals. Closer examination of decision processes leading to the provision of high intensity care, such as life support in the ICU, is necessary.

Patient and family involvement in decisions about their health treatments is supported in Canadian law (for example, Ontario, 1996). Unfortunately, the policy found

in healthcare institutions, provincial, territorial and federal professional associations and law varies widely in its guidance for decisions about life support at the end-of-life (Health Law Institute, 2004). Canadian citizens value autonomy and therefore individual patient values and preferences are intended to influence the use of healthcare resources. For example, the informed consent process described in the Health Care Consent Act clearly requires deliberation during the decision-making process (Ontario, 1996). Indeed, healthcare professionals must obtain informed consent for treatments such as life support interventions following a process that includes describing the option(s) and alternative(s), explaining the expected benefits and harms, and the likely consequences of refusing the treatment (Ontario, 1996). The law specifies that this information should be weighed with the patient's known values and beliefs and in view of whether the patient's condition is likely to improve, remain the same, or deteriorate with or without the treatment (Ontario, 1996). Treatments such as life support interventions may be administered in an emergency and without consent until communication about the continuation of the treatment can be facilitated. Notwithstanding, within a reasonable time period thereafter the capable patient or the incapable person's substitute decision-maker must give or refuse consent to the emergency treatment provided (Ontario, 1996). Unfortunately, the law remains unclear about whether and in what circumstances treatment can be withheld or withdrawn from patients (Downie, 2000; Downie, 2004). Indeed, without such clarity, the law is being clarified in courtrooms at the expense of individual patients and their families (Downie, 2004). Therefore, despite the legal requirement that patients or their substitute decision-maker provide consent for life support treatments, there is continued conflict between the healthcare team and families about decisions to withhold or withdraw life support.

In particular, conflict occurs when the healthcare team deems life support treatment medically futile but family refuses to consent to withdrawing life support. Treatment that is deemed medically futile "offers no reasonable hope of recovery or improvement or the person is permanently unable to experience any benefit" (Boards of Directors of the Canadian Healthcare Association, the Canadian Medical Association, the Canadian Nurses Association, & the Catholic Health Association of Canada, 2005, p. 5).

Some institutions set out to develop futility policies that will enable the clinician team to unilaterally withdraw care (Wear, Phillips, Shimmel, & Banas, 1995; Volker, 2004; Tan, Chun, & Kim, 2003; Tai & Lew, 1998; Singer et al., 2001; Rivin, 1997; Mercurio, 2005; Svantesson, Sjokvist, & Thorsen, 2003; College of Physicians & Surgeons of Manitoba, 2008). However, Downie (2004), a Canada Research Chair in Health Law and Policy, feels that unilateral decision-making in the clinical setting with regards to the withdrawal or withholding of life support “violates the strong social commitment to dignity as it is understood and reflected in [Canadian] law” (p. 149). Instead, Downie proposes an end-of-life policy that requires communication with a substitute decision-maker, resolution of conflict between patients/families and healthcare professionals, transfer of care if possible, and lastly, that the healthcare team seek recommendation(s) for non treatment from the court. Consistent with this recommendation, other futility policies require that the healthcare team engage in a process that strengthens communication and delineates the steps prior to taking legal action against families (Rocker & Dunbar, 2005; Mercurio, 2005; Kopelman, Parker, Ho, Jr., Willson, & Kopelman, 2005). Interestingly, hospitals with such futility policies noted that once there was greater communication between the family and the healthcare team, there was no need to turn to the policy’s further direction about declaration of futility (Wear et al., 1995; Wear & Logue, 1995). Other studies have also shown that proactive communication between healthcare professionals and families increased their agreement about using life support and resulted in earlier transition to comfort care in ICU when life support no longer met the needs of the patient (Lilly et al., 2000; Dowdy, Robertson, & Bander, 1998; Campbell & Guzman, 2003). Therefore, instead of a futility approach that delineates the hospital or healthcare system rights in legal action against families, healthcare teams may need to invest in timely communication with families and patients to facilitate the decision-making process about life support in ICU.

Despite the requirement for timely communication leading to informed consent, healthcare professionals seem to base their decisions about life support on factors other than patient/family wishes or values. Poor integration of patient or family wishes or values is one characteristic of a bad death (Institute of Medicine, 1997). The right

decision about whether or not to use life support depends on the individual patient's health situation, the options available to them and their values associated with the options. Values in the context of decision-making are the individual's judgment of the desirability / undesirability of specific elements of an option such as the procedures, mode of delivery, timing, and/or duration involved in undergoing a treatment; the expected physical, emotional, and social effects; and the chances of experiencing a particular physical, emotional, or social outcome (O'Connor, Llewellyn-Thomas, Dolan, Kupperman, & Wills, 2005). Unfortunately, the choice to receive life support in ICU is not explained by patient values or preferences (Somogyi-Zalud, Zhong, Hamel, & Lynn, 2002; Barnato et al., 2007) but is influenced by other factors such as age of the patient (Hamel et al., 1999; Johnson & Kramer, 2000), physician preferences (Garland, Connors, Garland, & Connors, 2007; Schneiderman, Kaplan, Pearlman, & Teetzel, 1993; Schneiderman, Kaplan, Rosenberg, & Teetzel, 1997; Ferrand et al., 2001; Hall & Rocker, 2000; Larochelle, Rodriguez, Arnold, & Barnato, 2009), or employment status (Guyatt et al., 2003). Therefore, there is a clear need to strengthen the influence of an individual patient's values and preferences on the decision about life support while they are critically ill.

The extent to which an individual patient's values and preferences influence the decision about life support may be related to the quality of communication with patients and families during the process of decision-making. Unfortunately, poor communication with patients and families about life support is a problem in the ICU. In a teaching hospital in the United States, none of the patients admitted to the ICU who subsequently died had palliative care or end-of-life care discussed as an alternative to life support prior to their ICU admission (Rady & Johnson, 2004). A study of physician-family conferences in the ICU about end-of-life treatment decisions concluded that only one of these conferences met all criteria for informed decision-making (White, Braddock, III, Bereknyei, & Curtis, 2007). This is consistent with studies from other clinical areas that show that patient and family engagement in the decision-making process has not been achieved (Elwyn et al., 2003; Guimond et al., 2003; Makoul, Arntson, & Schofield, 1995; McKinstry, 2000). For example, family conferences to formalize the decision-making

process are being held late in the process to resolve issues after there are already problems with communication (Marbella, Desbiens, Mueller-Rizner, & Layde, 1998; Schneiderman, Gilmer, & Teetzel, 2000; Schneiderman et al., 2003; Schneiderman, 2006; The Writing Group for the SUPPORT Investigators, 1995). As well, deliberation does not always include relevant team members: respiratory therapists and nurses in critical care areas have experienced moral distress related to withdrawal and prolongation of life-sustaining treatment which they attributed to being required to implement the decision without being invited to voice their dissent (Gutierrez, 2005; Chambliss, 1996; Caplan et al., 1995). Families in ICU also suffer significant distress related to end-of-life decision-making (Abbott, Sago, Breen, Abernethy, & Tulskey, 2001; Swigart, Lidz, Butterworth, & Arnold, 1996; Tilden, Tolle, Nelson, Thompson, & Eggman, 1999). The situation has prompted clinical practice guidelines recommending improved communication between and among families and their healthcare professionals in ICU to improve the quality of end-of-life care (Davidson et al., 2007; Rocker & Dunbar, 2005). Taken together, the current situation clearly suggests that there is a gap between ideal communication with patients and families during the decision-making process about life support and the current practice of healthcare professionals in ICU.

The nature of communication with patients and families that is considered ideal during the decision-making process is consistent with shared decision-making. Shared decision-making (SDM) is defined as a collaboration by healthcare professionals with patients and their family members to ensure an integrated and cohesive approach to the process of making health decisions (Legare, Stacey, Gagnon et al., 2010; Legare, Stacey, Pouliot et al., 2010). A systematic review of interventions for improving the adoption of SDM by healthcare professionals showed that educational meetings, receiving performance feedback, educational materials and patient decision aids (DAs) may be helpful to facilitate an SDM approach (Legare, Ratte et al., 2010). DAs are evidence-based resources designed to present decisions in a way that is accessible to patients and families. They provide information on the alternative options along with features of the options including both benefits and harms (Elwyn et al., 2006; O'Connor, Graham, & Visser, 2005). DAs facilitate informed consent by improving knowledge about the

options and their outcomes and increasing accurate risk perception which results in a better match between values and choices and reduces decisional conflict (O'Connor et al., 2009). Therefore in order to facilitate an SDM approach, a novel DA was developed using International Patient Decision Aid Standards (IPDAS) (Elwyn et al., 2006) to assist family members facing decisions about life support for a relative in the ICU.

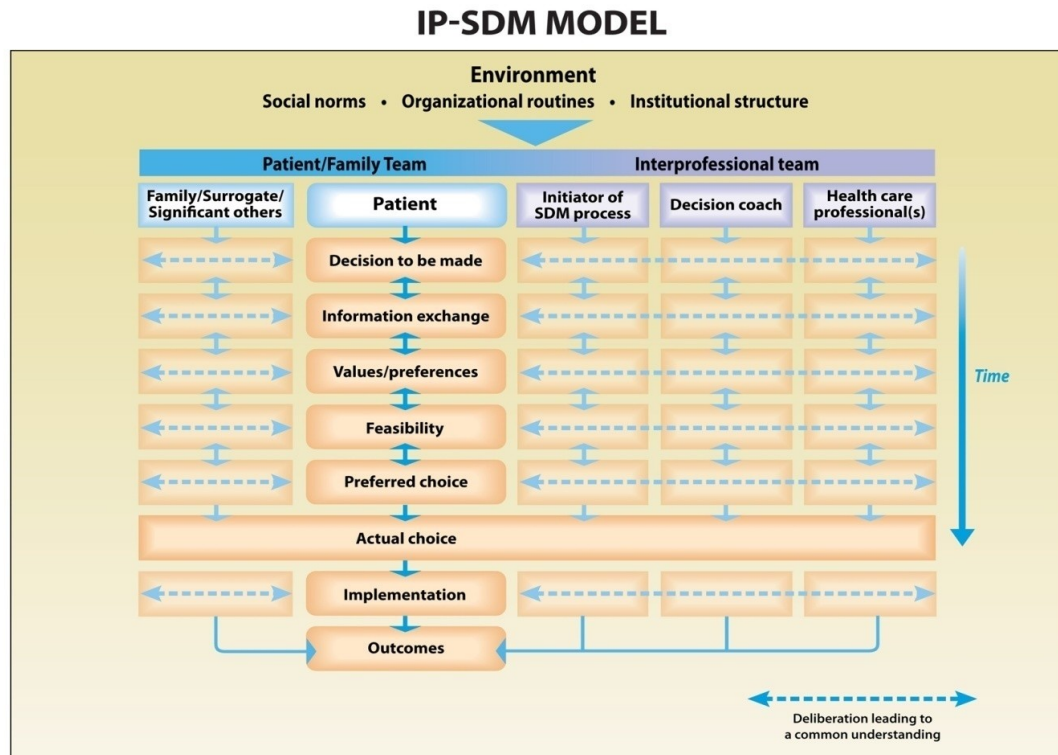
Guiding Conceptual Models

Two conceptual models guided the research undertaken during the dissertation. The Interprofessional Shared Decision Making (IP-SDM) model was used to understand and structure an interprofessional approach to the decision-making process in the ICU setting (Legare, Stacey, Gagnon et al., 2010). The International Patient Decision Aids (IPDAS) criteria guided the systematic development process used to develop and field test the novel DA to enhance family preparation for engagement in the decision-making process about life support for their relative in ICU (Elwyn et al., 2006).

The Interprofessional Shared Decision Making (IP-SDM) model

The Interprofessional Shared Decision Making (IP-SDM) model offered the structure needed to consider how the values and preferences of multiple healthcare professionals and family members influenced the decision about life support for the critically ill patient (Figure 1) (Legare, Stacey, Gagnon et al., 2010). Specifically, the IP-SDM model guided the analysis of barriers to SDM (Chapter 3) and the content and delivery of the DA intervention (Chapter 4). The model was considered potentially useful in ICU because it looks beyond the traditional physician-patient dyad widely recognized to influence the health decision-making process (Braddock, III et al., 2008; Charles, Gafni, & Whelan, 1997; Emanuel & Emanuel, 1992; Makoul & Clayman, 2006; Towle & Godolphin, 1999).

Figure 1 The Interprofessional Shared Decision Making (IP-SDM) Model



Note. From “Validating a conceptual model for an interprofessional approach to shared decision-making: A mixed methods study” by F. Legare, D. Stacey, S. Gagnon and colleagues, 2010, *Journal of Evaluation in Clinical Practice*, p. 4. Copyright 2010 by Blackwell Publishing Ltd (Wiley). Reprinted with permission.

The model identifies key stakeholders in SDM: the patient, family member(s), and members of the interprofessional healthcare team. While the model does not further articulate the concept of family, other literature suggests that family includes the substitute decision-maker and others who are designated by the patient (Wright & Leahey, 2009). In addition to their discipline specific roles, the IP-SDM model identifies two distinct roles for healthcare professionals in the decision-making process: to initiate the process and to provide non-directive support (decision coaching) to the patient and family during SDM. Consistent with the decision coaching role, family nursing research

suggests that nurses intervene in cognitive, affective and behavioural domains of family functioning by offering questions to prompt reflection and understanding, commending family strengths, offering information and opinions, validating or normalizing emotional responses, encouraging the telling of illness narratives, drawing forth family support, encouraging family members to be caregivers and offering caregivers support, encouraging respite, and devising rituals (Wright & Leahey, 1999; Wright, Watson, & Bell, 1996; Van Horn, Fleury, & Moore, 2002; Limacher & Wright, 2003; Johnson, Cook, Giacomini, & Willms, 2000; Duhamel, Dupuis, Reidy, & Nadon, 2006; Duhamel & Talbot, 2004; Bohn, Wright, & Moules, 2003). Further, the need to “establish reciprocity between the nurse’s ideas and opinions and the family’s illness experience” (Wright & Leahey, p. 155) seems consistent with the concept of deliberation presented in the IP-SDM model and lends support for the role of the nurse in facilitating deliberation as part of her practice with families. In the delivery of the DA intervention (Chapter 4), the nurse provided decision coaching to facilitate deliberation.

Key stages of the decision-making process include identifying a decision point, exchange of information, values or preference construction, considering feasibility of the options, identifying preferred choice, negotiating the actual choice, implementing the choice, and evaluating health outcomes (Legare, Stacey, Gagnon et al., 2010). During SDM, key stakeholders are described to engage in deliberation: authentic, constructive and open/honest communication leading to a common understanding towards the goal of high quality health decision (Legare, Stacey, Gagnon et al., 2010). Beyond the clinical encounters in which deliberation about decision-making would occur among stakeholders, the IP-SDM model identifies three factors that may impact engagement in SDM: social norms, organizational routines (i.e. “the way we do things” in clinical settings) and institutional/structural factors (i.e. federal or provincial/state or professional regulations) (Legare, Stacey, Gagnon et al., 2010). The IP-SDM model has been validated in primary care settings but not in the ICU setting.

The International Patient Decision Aid Standards (IPDAS) Criteria

The International Patient Decision Aid Standards (IPDAS) collaboration, representing an international group of researchers, healthcare professionals, and other stakeholders, established a set of criteria to determine the quality of patient decision aids (DAs) (Table 1) (Elwyn et al., 2006). The criteria are related to recommendations for a systematic development process, optimizing content (for example providing information about options, clarifying and expressing values, guiding coaching, and using plain language), and establishing effectiveness. IPDAS suggested that a systematic development process for DAs should: 1) review the evidence, 2) find out what users need to discuss options, and 3) field test with users (Elwyn et al., 2006). Table 2 summarizes and locates the six chapters of the dissertation showing the relationships between elements of the systematic development process with the study objectives and methods. The IPDAS criteria have set a benchmark for the systematic development of DAs and have been used as a basis for developing a validated instrument for assessing internal quality of DAs (Elwyn et al., 2009) and for measuring the impact of such tools (Entwistle et al., 2005; Kryworuchko, Stacey, Bennett, & Graham, 2008). However, elements of the systematic development process were included in the list of criteria based on a rating of their importance rather than feasibility or measurability (Elwyn et al., 2006) and they have not been explicitly operationalized in the development of DAs. Therefore, in addition to contributing knowledge about a novel DA to improve communication with families in ICU about the life support decision, the dissertation also contributes to an understanding of the feasibility and measurability of the proposed criteria for systematic development of DAs.

Table 1 International Patient Decision Aids Standards (IPDAS) Criteria

Criteria Related to Content of the Patient Decision Aid (DA)	
The DA provides information about options in sufficient detail for decision making	<input type="checkbox"/> describe the health condition <input type="checkbox"/> list the options <input type="checkbox"/> list the option of doing nothing <input type="checkbox"/> describe the natural course without options <input type="checkbox"/> describe procedures
If the DA is to provide information about tests, meets additional criteria.	<input type="checkbox"/> describe what test is designed to measure <input type="checkbox"/> include chances of true positive, true negative, false positive, false negative test results <input type="checkbox"/> describe possible next steps based on test result <input type="checkbox"/> describe positive features [benefits] <input type="checkbox"/> include chances the disease is found with / without screening <input type="checkbox"/> describe negative features of options [harms / side effects / disadvantages] <input type="checkbox"/> include chances of positive / negative outcomes <input type="checkbox"/> describe detection / treatment that would never have caused problems if one was not screened
The DA presents probabilities of outcomes in an unbiased and understandable way	<input type="checkbox"/> use event rates specifying the population and time period <input type="checkbox"/> allows the patient to select a way of viewing probabilities [words, numbers, diagrams] <input type="checkbox"/> compare outcome probabilities using the same denominator, time period, scale <input type="checkbox"/> describe uncertainty around probabilities <input type="checkbox"/> use visual diagrams <input type="checkbox"/> use multiple methods to view probabilities [words, numbers, diagrams] <input type="checkbox"/> allow patient to view probabilities based on their own situation [e.g. age] <input type="checkbox"/> place probabilities in context of other events <input type="checkbox"/> use both positive and negative frames [e.g. showing both survival and death rates]
The DA includes methods for clarifying and expressing patients' values	<input type="checkbox"/> describe the procedures and outcomes to help patients imagine what it is like to experience their physical, emotional, social effects <input type="checkbox"/> ask patients to consider which positive and negative features matter most <input type="checkbox"/> suggest ways for patients to share what matters most with others
The DA includes structured guidance in deliberation and communication	<input type="checkbox"/> provide steps to make a decision <input type="checkbox"/> suggest ways to talk about the decision with a health professional <input type="checkbox"/> include tools [worksheet, question list] to discuss options with others
Criteria Related to the Development Process	
The DA presents information in a balanced manner	<input type="checkbox"/> able to compare positive / negative features of options <input type="checkbox"/> shows negative / positive features with equal detail [fonts, order, display of statistics]
The DA has a systematic development process	<input type="checkbox"/> includes developers' credentials / qualifications <input type="checkbox"/> finds out what users [patients, practitioners] need to discuss options <input type="checkbox"/> has peer review by patient / professional experts not involved in development and field testing <input type="checkbox"/> is field tested with users [patients facing the decision; practitioners presenting options] The field tests with users [patients, practitioners] show the patient

	<p>decision aid is:</p> <ul style="list-style-type: none"> <input type="checkbox"/> acceptable <input type="checkbox"/> balanced for undecided patients <input type="checkbox"/> understood by those with limited reading skills
The DA uses up to date scientific evidence that is cited in a reference section or technical document	<ul style="list-style-type: none"> <input type="checkbox"/> provides references to evidence used <input type="checkbox"/> report steps to find, appraise, summarizes evidence <input type="checkbox"/> report date of last update <input type="checkbox"/> report how often patient decision aid is updated <input type="checkbox"/> describe quality of scientific evidence [including lack of evidence] <input type="checkbox"/> uses evidence from studies of patients similar to those of target audience
The DA discloses conflicts of interest	<ul style="list-style-type: none"> <input type="checkbox"/> report source of funding to develop and distribute the patient decision aid <input type="checkbox"/> report whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid
The DA uses plain language	<ul style="list-style-type: none"> <input type="checkbox"/> is written at a level that can be understood by the majority of patients in the target group <input type="checkbox"/> is written at a grade 8 equivalent level or less according to readability score [SMOG or FRY] <input type="checkbox"/> provides ways to help patients understand information other than reading [audio, video, in-person discussion]
If DA is internet based, meets additional criteria.	<ul style="list-style-type: none"> <input type="checkbox"/> provide a step-by-step way to move through the web pages <input type="checkbox"/> allow patients to search for key words <input type="checkbox"/> provides security for personal health information entered into the decision aid <input type="checkbox"/> make it easy for patients to return to the decision aid after linking to other web pages <input type="checkbox"/> provide feedback on personal health information that is entered into the patient decision aid <input type="checkbox"/> permit printing as a single document
If stories are used in the DA, meets additional criteria.	<ul style="list-style-type: none"> <input type="checkbox"/> use stories that represent a range of positive and negative experiences <input type="checkbox"/> state in an accessible document that the patient gave informed consent to use their stories <input type="checkbox"/> reports if there was a financial or other reason why patients decided to share their story
Criteria Related to Effectiveness	
The DA supports decision processes leading to decision quality	<p>The DA helps patients to ...</p> <ul style="list-style-type: none"> <input type="checkbox"/> recognize a decision needs to be made <input type="checkbox"/> know options and their features <input type="checkbox"/> understand that values affect decision <input type="checkbox"/> be clear about option features that matter most <input type="checkbox"/> discuss values with their practitioner <input type="checkbox"/> become involved in preferred ways
The DA ensures decision making is informed and values based (Decision quality)	<ul style="list-style-type: none"> <input type="checkbox"/> improves the match between the chosen option and the features that matter most to the informed patient

Note. Adapted from "Developing a quality criteria framework for patient decision aids: online international Delphi consensus process" by G. Elwyn, A. O'Connor, D. Stacey, R. Volk, A. Edwards, A. Coulter et al., 2006, BMJ Data supplement, doi: 10.1136/bmj.38926.629329.AE, Table 3. Copyright 2006 by BMJ Publishing Group Limited. Reprinted with permission.

Table 2 Relationship of Dissertation Content to Systematic Development Process

Chapter	Chapter Title	IPDAS Process	Objectives	Method
1	Introduction and Organization of the Dissertation	-	To describe the problem from nursing clinical practice and guiding conceptual models	
2	(Manuscript) Interventions for shared decision-making about life support in the Intensive Care Unit: A systematic review	Review the evidence	To explore the effectiveness of interventions to improve communication between the healthcare team, patients, their family members and surrogate decision-makers about the decision to use life support in the Intensive Care Unit	Systematic Review
3	(Manuscript) Family involvement in the process of decision-making about life support in the Intensive Care Unit: A qualitative study	Find out what users need to discuss options	To explore family involvement in decisions about life support interventions in the Intensive Care Unit	Qualitative study
4	(Manuscript) Field testing a patient decision aid to engage families in decision-making about life support in the Intensive Care Unit	Field test with users	To evaluate the ability to operationalize the IPDAS criteria in the context of field testing a novel DA for families facing decisions about life support for their relative in the Intensive Care Unit	Mixed method study
5	Integrated Discussion	-	To integrate the dissertation content and identify potential directions for theory, nursing practice, education, and research	Descriptive synthesis
6	Contributions of Collaborators	-	To describe the role of manuscript co-authors	

Purpose of the Dissertation

In summary, the purpose of the dissertation was to develop and field test a novel patient decision aid to enhance family preparation to engage with healthcare professionals in the process of making the decision about life support for their relative in ICU. Guided by the IPDAS criteria, the specific objectives were:

1. To explore the effectiveness of interventions intended to improve communication between the healthcare team, patients, their family members and surrogate decision-makers about the decision to use life support in the ICU;
2. To explore family involvement in decisions about life support interventions in the ICU
3. To evaluate the ability to operationalize the IPDAS criteria in the context of developing and field testing a novel DA for families facing decisions about life support for their relative in the ICU setting.

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Chapter 2: Interventions for Shared Decision-Making about Life Support in the Intensive Care Unit: A Systematic Review

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Abstract

Background

Healthcare professionals and families make decisions about the use of life support for patients in the Intensive Care Unit, including decisions to withhold or withdraw life support at the end-of-life. Best practice guidelines recommend using a shared decision-making (SDM) approach to improve the quality of end-of-life decision-making but do not describe how this should be done in practice.

Aims

We wanted to know what elements of SDM had been tested to improve communication between healthcare professionals, patients and their family about the decision. Trials relevant to our review assessed whether these interventions were more effective than usual care.

Methods

A systematic review of randomized controlled trials of SDM interventions for the decision about using life support, limiting the use of life support, or withdrawing life support for hospitalized patients. We searched databases from inception to January 2011.

Results

Of 3162 publications, four unique trials were conducted between 1992 and 2005. Of four trials, three interventions were evaluated. Two studies of interventions including 3 of 9 elements of SDM did not report improvements in communication. Two studies of the same ethics consultation which included 8 of 9 elements of SDM did not evaluate the benefit to communication. The interventions were not harmful; they decreased family member anxiety and distress, shortened Intensive Care Unit stay, but did not affect patient mortality.

Implications for Research and Practice

Few studies have evaluated interventions to improve communication between healthcare professionals and patients/families when facing the decision about whether or not to use life support in the ICU. Interventions that include essential elements of SDM need to be more thoroughly evaluated in order to determine their effectiveness and health impact and to guide clinical practice.

Key words

Shared Decision Making, Patient Participation, Communication, Life support Care, Withholding Treatment, Systematic Review.

Introduction

Decisions about the use of life support in the Intensive Care Unit (ICU) are often referred to as end-of-life decisions because healthcare professionals tend to engage patients and their families in these decisions when there is a transition to withholding or withdrawing life support. Withholding refers to not using some life support, whereas withdrawal means providing comfort care and sedation while discontinuing life support. Fifty to ninety percent of all deaths in the ICU are preceded by decisions to withhold or withdraw life support (Ferrand, Robert, Ingrand, & Lemaire, 2001; Keenan et al., 1997; Prendergast & Luce, 1997)

These decisions require the careful consideration of many factors unique to the patient's situation and may include: diagnosis, prognosis, experience of illness, values, beliefs, hopes, fears, moral and ethical obligations (Canadian Nurses Association, Canadian Medical Association, Canadian Health Care Association, & Catholic Health Association of Canada, 1999; Rocker & Dunbar, 2005). In addition, a wide variability exists in the intensity of care provided to similar types of patients at the end-of-life that is not explained by patient preferences (Menec et al., 2004; Barnato et al., 2007; Wennberg, Fisher, Goodman, & Skinner, 2008). For example, studies have demonstrated that some patients' preferences about life support were not at all congruent with the treatment they received (Alpert & Emanuel, 1998; Danis, Gerrity, Southerland, & Patrick, 1988). In these and other instances, poor communication contributes to the neglect of patient preferences resulting in distress and dissatisfaction amongst both healthcare professionals and family members in ICU (Boyle, Miller, & Forbes-Thompson, 2005; Blackhall, Cobb, & Moskowitz, 1989; Hanson, Danis, & Garrett, 1997; Kirchhoff et al., 2000; Breen, Abernethy, Abbott, & Tulsky, 2001).

Best practice guidelines for critical care clinicians recommend using a shared decision-making approach to improve the quality of end-of-life decision-making (Davidson et al., 2007; Rocker & Dunbar, 2005; Registered Nurses Association of Ontario, 2002). Shared decision-making (SDM) is a process where healthcare professionals engage the patient and family or surrogate decision-maker in the following

essential elements of the SDM process: 1) define and/or explain the problem that needs to be addressed; 2) present the options that exist, 3) share perspectives on the relative benefits, risks and costs of the options raised; 4) elicit patient values and preferences including ideas, concerns, and outcome expectations; 5) discuss patient ability/self-efficacy to follow through with a plan; 6) explain doctor knowledge and recommendations given the situation at hand; 7) check and clarify understanding; 8) make or explicitly defer the decision; and 9) arrange follow-up (Makoul & Clayman, 2006). Although professionals may be clear about the elements to include in the SDM process and feel the push from guideline developers to simply change their practice, it is quite another task to integrate such an approach in practice.

Indeed, while we know that families want to be involved in decision-making about life support, there is evidence to show that this does not occur. A survey of 789 substitute decision-makers of ICU patients in Canada revealed that 81% preferred to take an active role in making end-of-life decisions with the physician (Heyland et al., 2003). Another study at one teaching hospital in the United States reported that none of the patients admitted to ICU who subsequently died had palliative care or end-of-life care discussed as an alternative to use of life support prior to ICU admission (Rady & Johnson, 2004). However, to comply with healthcare treatment consent regulations, patients and their families need to be able to consent for treatment knowing the alternative options that are available to them (Ontario, 1996; Washington State Legislature, 2007). A third study of physician-family conferences held in the ICU about end-of-life treatment decisions reported that only one of 51 conferences met all criteria for SDM and the mean shared decision-making score was 6.1(SD \pm 1.8) on a 10-point scale (White, Braddock, III, Bereknyei, & Curtis, 2007). Although families want to be involved in decisions about level of care in ICU, current practice is inadequate and interventions could improve the process of SDM.

Review Objectives

The review intends to explore the effectiveness of interventions to improve communication between the healthcare team, patients, their family members, and surrogate decision-makers about the decision to use life support in the ICU. Specific research questions were:

- 1) What elements of SDM have been tested in these interventions?
- 2) Are interventions that use SDM elements more effective than usual care?

Methods

The systematic review protocol was developed a priori based on the Cochrane Handbook for Systematic Reviews of Interventions (The Cochrane Collaboration, 2008) and the PRISMA statement (Liberati et al., 2009; 2008; Moher, Liberati, Tetzlaff, Altman, & The PRISMA Group, 2009). The criteria for determining study eligibility are listed in Table 1. We searched MEDLINE (1950 to January Week 2 2011), EMBASE (1980 to 2011 Week 2), CINAHL (1982 to January Week 1 2011), the Cochrane Central Register of Controlled Trials (CENTRAL, to 3rd Quarter 2008), and AMED (1985 to January 2011) using the Ovid/EBSCO interface without language restriction. The search strategy was developed using the highly sensitive search strategy for randomized controlled trials (2006) with the expertise of a library scientist (see Figure 1 for MEDLINE search strategy). The search was then adapted for the other databases. We also reviewed Dissertation Abstracts International (1861 to 1 February 2007), web based registries of clinical trials (*National Institute of Health and National Library of Medicine ClinicalTrials.gov*, *Current Controlled Trials*, *Australian Clinical Trials Registry*) and reference lists of included studies and relevant review articles. Relevant conference, symposium and colloquium proceedings and abstracts (*5th International Consensus Conference on the Challenges in End-of-life Care in the ICU in 2003*; and *International Shared Decision Making Conferences from 2005-2009*) were hand searched.

Table 1 Criteria for Study Inclusion

Criteria	Included	Excluded
Population	Adults (patient, and family members and/or healthcare team members) making decisions for patients (any age)	All other
Intervention	Intervention to improve communication about decisions to use life support, to continue or limit the use of life support, or to withhold or withdraw life support for hospitalized adults or children	Interventions regarding decisions that were solely about feeding, hydration, comfort or symptom control including palliative care services (i.e. life support not discussed as an alternative), or were administered in the community about a hypothetical decision (i.e.: Advanced Directives).
Comparison	Usual care group / Alternative intervention for end-of-life decision-making	N/A
Outcomes	<p>1) Evidence for decision quality (i.e. being informed and making a decision based on patient values or preferences)</p> <p>2) Evidence of shared decision-making process (i.e. preparation for decision-making, role in decision-making or agreement about the decision)</p> <p>3) Impact of the intervention on Patients (i.e. all cause mortality);</p> <p>4) Impact of the intervention on Family members, surrogate decision-makers, or healthcare team members (i.e. anxiety, distress, satisfaction with process or decision regret);</p> <p>5) Impact of the intervention on Healthcare system (i.e. measures of resource use such as types of treatments used or length of stay in ICU or in hospital).</p>	N/A
Design	Randomized controlled trials	All other
Languages	All languages (English, French, Other)	N/A

Figure 1 MEDLINE Search Strategy

Type of study:

1. randomized controlled trials.sh.
2. randomized controlled trial.pt.
3. controlled clinical trial.pt.
4. random allocation.sh.
5. double blind method.sh.
6. single blind method.sh.
7. or/1-6
8. (ANIMALS not HUMANS).sh.
9. 7 not 8
10. clinical trial.pt.
11. exp CLINICAL TRIALS/
12. (clin\$ adj25 trial\$).ti,ab.
13. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab.
14. PLACEBOS.sh.
15. placebo\$.ti,ab.
16. random\$.ti,ab.
17. RESEARCH DESIGN.sh.
18. or/10-17
19. 18 not 8
20. 19 not 9
21. COMPARATIVE STUDY.pt.
22. exp EVALUATION STUDIES/
23. FOLLOW UP STUDIES.sh.
24. PROSPECTIVE STUDIES.sh.
25. (control\$ or prospectiv\$ or volunteer\$).ti,ab.
26. or/21-25
27. 26 not 8
28. 27 not (9 or 20)
29. 9 or 20 or 28

Setting:

30. exp Intensive Care/
31. exp Intensive Care Units/
32. Critical Care/ or critical illness/
33. (intensive care or icu).tw.
34. or/30-33

Interventions:

35. exp Decision Making/
36. (decide or deciding or decision\$).tw.
37. exp Decision Support Techniques/
38. Communication/
39. communicat\$.tw.
40. Cooperative Behavior/
41. (collaborat\$ or cooperat\$).tw.
42. Interdisciplinary Communication/ or interprofessional relations/ or patient care team/
43. (interdisciplinary or multidisciplinary).tw.
44. Patient participation/ or consumer participation/ or Physician-nurse relations/ or doctor nurse relation/ or patient compliance/ or patient care planning/
45. Professional-Family Relations/ or Family Nursing/

46. (family adj (centered or focused or meeting\$ or conference\$)).tw. or family/px
47. or/35-46

Focus of review:

48. exp Withholding Treatment/

49. Palliative Care/ or Life Support Care/ or terminal care/ or hospice care/ or resuscitation orders/

50. Living Wills/ or third-party consent/ or parental consent/ or informed consent/ or right to die/ or treatment refusal/

51. (passive euthanasia or resuscitat\$ or end-of-life).tw.

52. ((withhold\$ or withdraw\$ or cessation) adj2 (care or treatment\$ or resuscitation)).tw.

53. or/48-52

54. 29 and 34 and 47 and 53

Two reviewers (JK, EH) independently screened identified titles and abstracts and then the full text of all potentially relevant reports to reach consensus on included studies. Two reviewers (JK, MAM) used a standardized form to extract a description of the life support decision, intervention and comparison group(s), participant characteristics, outcomes and risk of bias. The intervention content was summarized according to the elements of shared decision making (Makoul & Clayman, 2006). Outcomes were described in natural units, with the difference in means reported for continuous data. Risk ratios with 95% confidence intervals were used to compare data about discrete events. Clinical heterogeneity in the populations and interventions made combination of study results undesirable and impractical.

Results

Of 3162 reports identified, we included four unique RCTs that evaluated three different interventions (Figure 2). We excluded 18 intervention studies (Table 2) which did not meet the study design criteria (Ahrens, Yancey, & Kollef, 2003; Baumann-Holzle, Maffezzoni, & Bucher, 2005; Burns et al., 2003; Campbell & Guzman, 2003; Daly et al., 2010; Dowdy, Robertson, & Bander, 1998; Holloran, Starkey, Burke, Steele, Jr., & Forse, 1995; Holzapfel, Demingon, Piralla, Biot, & Nallet, 2002; Jacobowski, Girard, Mulder, & Ely, 2010; Lecuyer et al., 2007; LaPuma, Stocking, Silverstein, DiMartini, & Siegler, 1988; Lilly et al., 2000; Machare et al., 2009; Mello et al., 2004; Mosenthal & Murphy, 2006; Norton et al., 2007; O'Mahony et al., 2010; Penticuff & Arheart, 2005;). The four included studies are described here. Three trials randomized at

the patient level (Schneiderman, Gilmer, & Teetzel, 2000; Schneiderman et al., 2003; Lautrette et al., 2007) and one randomized at the practitioner level (The Writing Group for the SUPPORT Investigators (SUPPORT), 1995) (Table 3). Three of the studies enrolled family of ICU patients for whom the healthcare team felt that treatment was futile because adult patients would die within a few days (Lautrette et al., 2007) or for whom values based conflicts arose during ICU admission (Schneiderman et al., 2000; Schneiderman et al., 2003). The other study enrolled seriously ill hospitalized patients (SUPPORT, 1995). In general, the decision at end-of-life was conceptualized as a dichotomous choice: comfort care or using life support technology.

Figure 2 Flow of Information through the Systematic Review Process

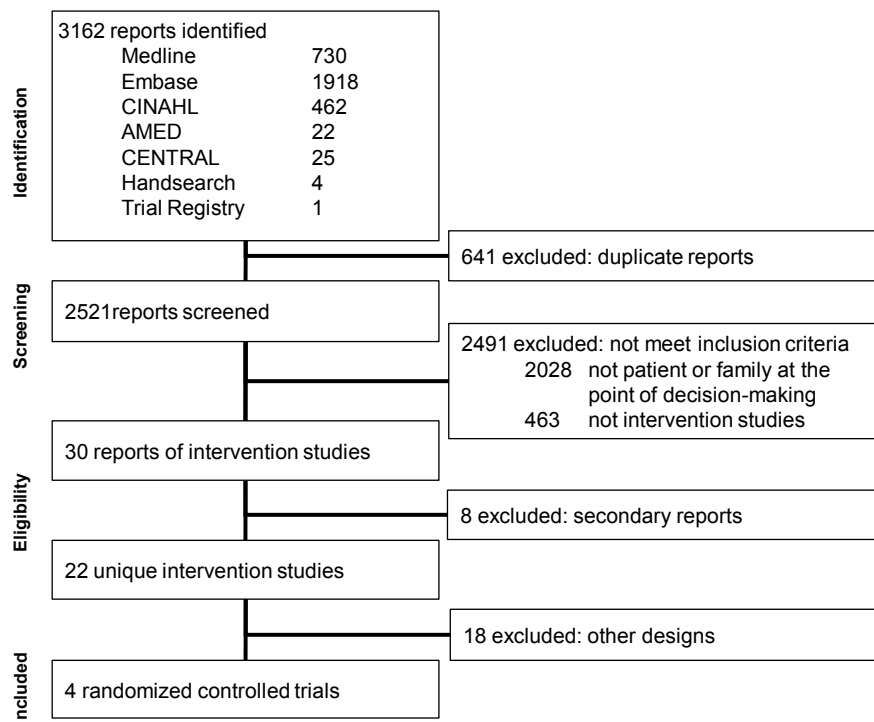


Table 2 Excluded Intervention Studies

Study	Design leading to exclusion
LaPuma 1988	Prospective intervention group only pretest/ posttest
Holloran 1995	Prospective pre/post nonequivalent control group design
Dowdy 1998	Prospective pre/post nonequivalent control group design
Lilly 2000	Prospective pre/post nonequivalent control group design
Holzapfel 2002	Prospective intervention group posttest study
Ahrens 2003	Prospective controlled trial
Burns 2003	Prospective pre/post control group design
Campbell 2003	Retrospective/Prospective cohort comparison
Mello 2004	Prospective pre/post control group design
Baumann-Holzle 2005	Prospective matched control study
Penticuff 2005	Prospective pre/post control group design
Mosenthal 2006	Prospective before/after controlled study
Lecuyer 2007	Prospective intervention group posttest study
Norton 2007	Prospective pre/post nonequivalent control group design
Machare 2009	Prospective feasibility study intervention group only
Daly 2010	Prospective before/after controlled study
Jacobowski 2010	Prospective before/after controlled study
O'Mahony 2010	Prospective post test non-equivalent control group

Table 3 Characteristics of Included Studies

Characteristic	SUPPORT 1995	Schneiderman 2000	Schneiderman 2003	Lautrette 2007
Design	Cluster randomized controlled trial	Patient randomized controlled trial	Patient randomized controlled trial, stratified by ICU	Patient randomized controlled trial, stratified by ICU
Date	1992-1994	1997-1998	2000-2002	2005
#Participants (Intervention, Control)	4804 (2652, 2152)	74 (37, 37)	551 (278, 273)	126 (63, 63)
Analysis	Available case, Intention to treat	Available case	Available case	Available case, Intention to treat
Sample	Subgroup analysis of adult seriously ill hospitalized patients admitted to ICU	Adult ICU patients in whom value based conflicts arose between health care team or team and family/ Family members	Adult ICU patients in whom value based conflicts arose between health care team or team and family	Adult ICU patients whose physician believed they would die within a few days
Country	US	US	US	France
Setting	Medical and surgical ICUs in 5 academic teaching hospitals	Medical and surgical ICU in 1 academic teaching hospital	Medical and surgical ICUs in 7 academic teaching hospitals	Medical and surgical ICUs in 7 general hospitals and 15 academic teaching hospitals
Objective	To improve end-of-life decision-making and reduce frequency of mechanical support, painful and prolonged processes of dying	To determine whether ethics consultation could reduce the number of days of non-beneficial treatment for patients who do not survive to discharge	To determine whether ethics consultation could reduce the number of days of non-beneficial treatment for patients who do not survive to discharge	To examine the impact of a brochure and a structured end-of-life conference on family bereavement
Intervention	Specially trained nurse to encourage communication	Ethics consultation	Ethics consultation	Proactive end-of-life conference and bereavement

	between patient and physician		brochure
Outcomes	Proportion of Advanced Care Planning discussions, prognostic/ preference reports received, Prognostic discussions, Resuscitation discussions, Agreement with decision to forego resuscitation, Patient mortality, ICU/Hospital resource use.	Satisfaction with the intervention, Patient mortality, ICU resource use.	Agreement with recommendations, Patient mortality, ICU resource use.
			Family distress and anxiety, Number of families informed of decision to withdraw life support, Clarity of information, Need for additional information, Time family spent talking, Proportion of families expressing patient /own wishes, Agreement with decision to forego resuscitation. ICU resource use.

We examined the three interventions that were trialled using the SDM framework. One intervention addressed 8 of 9 essential elements of SDM in two studies of an ethics consultation (Schneiderman et al., 2000; Schneiderman et al., 2003), while the interventions in the other two studies each addressed less than half of the essential elements of SDM (SUPPORT, 1995; Lautrette et al., 2007) (Table 4). The studies of ethics consultation attempted to resolve conflict between the healthcare team and families by analyzing problems within an ethical framework using relevant policies and case law (Schneiderman et al., 2000; Schneiderman et al., 2003). During ethics consultation, the ethics consultant focused on exploring the problem with the family and the healthcare team to identify and explore options available, identify conflict and articulate areas of consensus and disagreement, clarify patient values and preferences, and develop consensual goals and treatment plans (Schneiderman et al., 2000; Schneiderman et al., 2003). The only element of SDM not discussed was ability or self efficacy for decision-making. The specially trained nurse for the SUPPORT study interviewed patients, families or physicians separately to elicit preferences for resuscitation, improve understanding of outcomes, evaluate pain control, and facilitate advanced care planning. Then the SUPPORT study provided reports of these preferences and outcomes to the attending physician as well as regular prognostic estimates of 6 month survival and outcomes of cardiopulmonary resuscitation (CPR) and estimates of functional disability within two months of admission (SUPPORT, 1995). In Lautrette and colleagues' study, the structured family conference was designed to prevent conflict when family were informed of the physician's recommendation to forego life sustaining treatment. The physician used the mnemonic *VALUE* to structure the family conference which reminded them to *Value* and appreciate what family members said in the family conference, *Acknowledge* their emotions, *Listen*, ask questions that would allow the team to *Understand* who the patient was as a person, and *Elicit* questions from the family members (Lautrette et al., 2007). Family members were also provided with a brochure on bereavement (Lautrette et al., 2007). Therefore, it was possible to highlight which aspects of SDM were included in the interventions.

Table 4 Elements of Shared Decision Making in Interventions

Essential elements of SDM *	SUPPORT 1995	Schneiderman 2000; 2003	Lautrette 2007
Problem defined/ explained	No	✓	No
Options (including alternatives) presented	No	✓	No
Benefits/ risks/ costs of options discussed	✓	✓	No
Values/ preferences discussed	✓	✓	✓
Ability/self efficacy discussed	No	No	No
Doctor knowledge/ recommendations explained	No	✓	✓
Understanding assessed/ clarified	✓	✓	No
Decision made or explicitly deferred	No	✓	✓
Follow-up arranged	No	✓	No

* Makoul & Clayman, 2006

The comparison group in all four trials received 'usual care'. Ethics consultation was available to patients in the usual care group as well if it was requested by the team and in some cases this occurred (Schneiderman et al., 2000; Schneiderman et al., 2003). The studies acknowledged that end-of-life family conferences or communication occurred as part of usual care, but the structure and frequency of such conferences or communication were not described except in one study (Lautrette et al., 2007). Lautrette and colleagues' studied ICUs where three formal family meetings were led by the intensivist in charge of the patient: the first provided information about diagnosis, prognosis, and treatments; the second provided additional information about the course of illness in ICU, answered questions and checked that family understood the situation; and the third reviewed the patient's illness history and provided an update about the course of illness and treatments while in ICU with explanation of the patient's prognosis. Because

usual care was not always described and may contain some elements of SDM, it was difficult in most cases to assess the “added dose” of SDM that the interventions provide.

None of the studies met all five quality criteria related to aspects of methodology (Table 5). Only Lautrette and colleagues’ study was registered (Lautrette et al., 2007). None of the studies report blinding. One study randomized at the practitioner level (Lautrette et al., 2007) while the other three studies randomized at the patient level risking possible contamination if the clinicians changed their approach with control group patients (SUPPORT, 1995; Schneiderman et al., 2000; Schneiderman et al., 2003). Two studies had significant attrition for the measurement of family satisfaction which could result in an underestimate of effect: one study of ethics consultation had data for satisfaction with the intervention in 8 of 35 participants (Schneiderman et al., 2000) and family member distress and anxiety was assessed in 108 of 126 surrogates (Lautrette et al., 2007).

Table 5 Quality Appraisal

Quality Criteria	SUPPORT 1995	Schneiderman 2000	Schneiderman 2003	Lautrette 2007
Allocation concealment reported	No	No	✓	✓
Patient or clinician blinding to group assignment	No	No	No	No
Outcome assessor and data collector blind to group assignment	No	No	✓	✓
Attrition reported	No	✓	✓	✓
Study registered	No	No	No	✓

Decision Quality

None of the studies measured decision quality or its elements such as knowledge or congruence between values and choice.

Shared Decision Making Process

All four studies evaluated some elements of SDM. The SUPPORT study established that many patients in both groups would have liked to have a discussion about prognosis (43%), but there was no difference in the number of patients reporting such discussions (41% versus 39%) (SUPPORT, 1995). Also, there was no improvement of physician appreciation of patient preferences for care when compared with the patients stated preferences (adjusted ratio, 1.22; 95% CI 0.99-1.49) (SUPPORT, 1995). This may be due in part to the challenges delivering the intervention in the SUPPORT study. For example, the specially trained study nurse spoke directly with many patients or family surrogates to generate a printed report of their understanding and preferences for their physician (78%). However, fewer physicians reported receiving this information (34 %) (SUPPORT, 1995). In one study of ethics consultation, participating families felt that the conference was responsive to personal values (Schneiderman et al., 2000). A structured family conference made no difference in the number of families informed of the decision to forego life support (100% versus 97%, $p=0.99$), while intervention group families needed less additional information after the conference (30% versus 46%, $p=0.05$), more frequently expressed the patient's wishes (70% versus 54%) and less frequently expressed their own wishes (70% versus 84%) (Lautrette et al., 2007). Taken together, there is some information about desire to receive information about risks of options (i.e. prognosis (SUPPORT, 1995)), contribution to family understanding and need for additional information after the intervention (Lautrette et al., 2007), and about aspects of values or preferences (Lautrette et al., 2007; SUPPORT, 1995; Schneiderman et al., 2000). However, studies did not evaluate how well the decision problem was explained, deliberation about options (including alternatives), patient or family member ability or self efficacy, professional's explanation of facts or recommendations, whether a decision was made, deferred, or the extent of follow-up.

Patient Mortality

There was no difference between intervention and control groups with respect to mortality measured at various time points in the included studies. In one study, the mortality rate was unchanged at six months (44% intervention versus 47% control) (SUPPORT, 1995). Two other studies measured this outcome until hospital discharge and found no difference (60% intervention and control (Schneiderman et al., 2000); 63% intervention versus 58% control, $p > 0.20$ (Schneiderman et al., 2003)). The fourth study reported that mortality rates were unchanged when the intervention was provided when physicians believed the patient would die within a few days (98% versus 97%, $p = 0.30$) (Lautrette et al., 2007).

Family Member Health Status

One study reported on the intervention's impact on family member health. The structured family conference decreased the presence of post traumatic stress disorder symptoms (45% versus 69%), decreased symptoms of anxiety (45% versus 67%) and decreased symptoms of depression (29% versus 56%) in family members (Lautrette et al., 2007).

Resource Use

Of the four trials, three measured length of stay in ICU and/or use of ventilation and other life support technologies. The SUPPORT study showed no difference in length of stay in ICU, days receiving mechanical ventilation or days spent in a coma before death (adjusted ratio, 0.97; 95% CI, 0.87 to 1.07) (SUPPORT, 1995). Studies of ethics consultation showed that the intervention group spent fewer days in ICU. In the single site trial, among the 21 patients in each group who died, intervention group patients had fewer days in ICU (13.2 days in ICU for the control group versus 4.2 days for the intervention group, no CI or SD given, $p = 0.03$) (Schneiderman et al., 2000). In the multi-site trial, intervention group patients spent fewer days in ICU from the day they entered the study to the day they died in hospital (the intervention group spent 6.42 days (SD 6.89 days) in ICU compared to the control group who spent 7.86 days (SD 10.48 days) in ICU (Schneiderman et al., 2003). Among those patients receiving ethics consultation,

there was decreased use of mechanical ventilation in patients who did not survive to discharge (mean 6.52 days [SD 8.52 days] versus 8.22 days [SD 11.16 days]) (Schneiderman et al., 2003). Finally, families receiving structured end-of-life conferences had longer conferences (median 30 minutes [IQR 19-45minutes] versus 20 minutes [IQR 15-30 minutes]) and spent more time talking than usual care families (median 14 minutes [IQR 8-20 minutes] versus 5 minutes [IQR 5-10minutes]) (Lautrette et al., 2007). Patients from both groups spent the same number of days in ICU (median 7 [IQR 4-14] versus 9 [IQR 5-20] while the intervention group withdrew more life support treatments than usual care controls (mechanical ventilation withdrawn 17% versus 14%, $p=0.03$; vasopressors withdrawn 51% versus 30%, $p=0.01$))

Discussion

This review is the first systematic synthesis of studies that evaluated the effectiveness of interventions to improve communication between the healthcare team, patients, their family members and surrogate decision-makers about the decision to use life support in the ICU. Four studies were identified which trialled three unique interventions. Ethics consultation addressed almost all essential elements of SDM (Schneiderman et al., 2000; Schneiderman et al., 2003), while SUPPORT's specially trained nurse and Lautrette and colleagues' structured family conference each addressed one-third of the essential elements. Although there was no effect on the number of patients/family engaged in discussions, those who did participate needed less additional information (Lautrette et al., 2007), felt the intervention was sensitive to their values (Schneiderman et al., 2000), and were able to focus on patient preferences rather than family preferences (Lautrette et al., 2007). Some studies found a reduction in length of stay in the ICU for the intervention group (Schneiderman et al., 2000; Schneiderman et al., 2003); however, the largest study showed no difference (SUPPORT, 1995). One study found that a structured family conference resulted in decreased symptoms of post-traumatic stress disorder, anxiety and depression among family members (Lautrette et al., 2007). The interventions did not affect mortality and showed mixed effects on the use of ventilation and other life support technologies: decreased use was shown by two studies

(Lautrette et al., 2007; Schneiderman et al., 2003) and no difference in use in the largest study (SUPPORT, 1995).

Elements of Shared Decision Making in Interventions

Although their systematic review of the literature describes SDM outside of the context of this decision, Makoul and Clayman considered that 9 elements were essential to engage patients, families and their healthcare team in SDM (Makoul & Clayman, 2006). Integrating all elements of SDM may also result in improvements in the quality of decision-making about life support in ICU. All trials included some of the essential elements of SDM. The SUPPORT trial included 3 of 9 essential elements of SDM through a specially trained nurse who involved patients in advance care planning and provided prognostic and preference reports to physicians but did not achieve improved communication about prognosis or knowledge of patient preferences for care and made no difference in number of days spent in ICU, receiving mechanical ventilation or comatose before death (SUPPORT, 1995). In particular, while the benefits/ risks/ costs of options and patient preferences and understanding were assessed/ clarified during that intervention, the failure of this intervention may validate the need to include other elements deemed essential to the SDM process. More recent efforts aimed at improving the structure and quality of communication with families are potentially more effective (Schneiderman et al., 2000; Schneiderman et al., 2003; Lautrette et al., 2007). These interventions included a structured ethics consultation and a structured family conference and brochure about bereavement. The structured ethics consultation included 8 of 9 elements of SDM and seemed to shorten length of stay and resource use (Schneiderman et al., 2000; Schneiderman et al., 2003). The structured family conference included 3 of 9 elements and resulted in decreased symptoms of post traumatic stress disorder, anxiety and depression among family members (Lautrette et al., 2007). Other interventions proven to be effective in enhancing shared decision making are patient decision aids. Interestingly, patient decision aids address only the first four of the essential SDM elements (Elwyn et al., 2006). But they are not intended to be used alone and therefore the other essential elements could be met in consultation with a healthcare provider

(O'Connor et al., 2003).

We next considered the role of health professionals in the clinical encounter to better understand how an intervention, once implemented, serves to address the essential elements of SDM. The roles of healthcare professionals in the SDM process were not clearly identified in the included studies. For example, the SUPPORT trial nurse provided support to both physicians and patients separately but was not a member of the healthcare team for the patient and so may not have been considered a legitimate source of support in the decision-making process (SUPPORT, 1995). In the other studies, the intervention focused on facilitating the role of the physician (Schneiderman et al., 2000; Schneiderman et al., 2003; Lautrette et al., 2007). Collaboration between healthcare professionals in SDM may be necessary to promote quality decision-making in a setting like the ICU, where typically healthcare professionals are more effective when they work in teams (Baggs, Norton, Schmitt, & Sellers, 2004). Several systematic reviews identify ten key elements of effective interprofessional collaboration: two or more health professionals from different disciplines, a common goal, collaborative relationships, integrated and cohesive care, symmetry of power, shared knowledge, interactions over time, common understanding of each others' role, interdependency among health professionals, and a supportive organizational environment (D'Amour & Oandansan, 2005; Reeves et al., 2008). Indeed, more recent models of SDM focus on supportive roles of nurses and other healthcare professionals in addition to the leadership role of physicians in decision-making (Legare et al., 2010; Murray, Miller, Fiset, O'Connor, & Jacobsen, 2004; Stacey et al., 2008). Decision coaching has been provided to patients and families by nurses (Kennedy et al., 2002; Lerman et al., 1997; Rothert, Holmes-Rovner, Rovner, & et al., 1997; Stacey, Taljaard, Drake, & O'Connor, 2008; Stacey, Chambers, Jacobsen, & Dunn, 2008; Stacey et al., 2008), pharmacists (Murray, 2009), counselors (Green, Biesecker, McInerney, Mauger, & Fost, 2001; Lerman et al., 1997; Murray, 2009), psychologists (Rothert et al., 1997), health educators (Myers et al., 2005), and university students (Belkora, Franklin, O'Donnell, Ohnemus, & Stacey, 2009). In the ICU environment, nurses and other healthcare professionals could assume this type of role in

the SDM process. A deeper understanding of various healthcare roles will likely help team members provide integrated and cohesive healthcare with the goal of achieving a higher quality decision about the use of life support interventions (College of Nurses of Ontario, 2009; Davidson et al., 2007).

Evidence of the Shared Decision Making Process

Based on our systematic review, there is insufficient evidence to conclude that SDM processes were either implemented or effective. While included studies reported on at least 15 different outcomes, the SDM process was incompletely evaluated and the quality of life support decision-making was not evaluated. Similarly, the 35 studies reviewed in the 2003 Cochrane review of decision aids measured 35 different primary outcomes, demonstrating that there was little consensus about how SDM ought to be evaluated (O'Connor et al., 2003; Kryworuchko, Stacey, Bennett, & Graham, 2008). In the studies included in our review, families were asked to withdraw or withhold life support as consent to the course of action offered by the physician, suggesting that clinicians may tend to use a more paternalistic style of decision-making for critically ill patients. We could not establish that the decision taken was informed since knowledge was not evaluated in any study. Until studies measure patient knowledge, values, informed preferences, and agreement between values and the decision taken, we will be unable to fully assess the level of improvement in decision quality (O'Connor et al., 2003). Existing measures of the SDM process, such as communication and collaboration with the healthcare team (Nelson, Mulkerin, & Adams, 2006) and patient and family involvement in the decision-making process (Elwyn et al., 2003) could be used to evaluate SDM in the ICU setting.

Regardless, a description of the mechanisms by which the interventions were expected to have an effect and a selection of outcome measures based on evaluating those effects are needed to allow reviewers to draw conclusions about the impact of these interventions. Anticipating the mechanism of effect may also direct the researcher's attention to participants in particular circumstances for whom an intervention may be particularly successful. For example, one of the studies excluded from this review

described a non-randomized trial of an intervention intended to strengthen parent-professional collaboration (Penticuff & Arheart, 2005). The intervention sought to improve parents' understanding of medically relevant information and included them in structured meetings to plan the infants' care. Though the intervention appeared to have little impact overall, subgroup analysis showed that the intervention was especially effective in improving understanding and collaboration in low-income, young, minority mothers (Penticuff & Arheart, 2005). An ideal evaluation plan must gauge the “dose” of intervention and usual care or other comparison, the impact on the processes of care, and the quality life support decision-making, as well as describe the potential health benefits to healthcare professionals, patients and families.

The decision about life support in the ICU is one that would seem appropriate for an SDM approach: this is a high stakes decision where there is more than one medically reasonable option, each with benefits and harms that people value differently, and without clear advantage in terms of health outcomes. In the included studies, the decision about life support was conceptualized as a dichotomous choice: comfort care or using life support technology. Comfort care and life support may also be confluent goals and it is not known whether this dichotomy represents families or clinicians' conceptualization of life support decision-making. For patients managing chronic illness, it has been noted that end-of-life decision-making occurs in an iterative fashion as they assess the impact of their illness on their physical, emotional and social life (Stacey et al., 2007). Health professionals could provide better support to families making these difficult decisions if we conceptualize end-of-life decision-making in ways that allow us to examine and improve the process which unfolds between clinicians and families.

Downstream Effects of Shared Decision Making

Implementing SDM for end-of-life decisions may affect participants in the process as well as the broader healthcare system in which the interventions are situated. The greatest benefits of a structured family conference and bereavement brochure were to decrease stress, anxiety and depression in bereaved families. The effect of the intervention trialled in France may have been more profound than what might have been

found in a North American setting because the comparator, usual care, is also very different (Lautrette et al., 2007). Participants in the ethics consultation intervention were satisfied, although no comparison was made to the control group (Schneiderman et al., 2000; Schneiderman et al., 2003). Although satisfaction with care has not been helpful to determine the effect of other decision support interventions (O'Connor et al., 2003), the Family Satisfaction with ICU Care (FS-ICU 24) sub-scale, Satisfaction with Decision Making, was developed and validated to measure family satisfaction in the critical care setting and has been used to identify areas for improvement in end-of-life care (Heyland et al., 2003; Stricker KH, Zwahlen M, Schmidlin K, Mohr U, & Rothan HU, 2009). Goals of the SDM process as measured in other studies also include satisfaction with the decision, self efficacy, perceptions of being supported and cared for and collaboration within the healthcare team, transition to home or palliative care, moral distress and role satisfaction among clinicians. Demonstrating a positive health impact on patients (i.e. quality of life), family members (i.e. less distress or facilitated grieving) and healthcare professionals (i.e. in terms of retention or decreased moral distress) may be necessary to justify the additional work required to engage in SDM. Certainly healthcare professionals should consider including performance and outcome measurements as a way to improve and be more accountable for their approach to SDM (Institute of Medicine, 2001).

The ideal length of stay in the ICU depends on the health state of the patient, the context of their illness and their values and preferences for care. While it may be reasonable to conclude that if patients die anyway, resources were not well utilized (this is the basic premise of futility and undesirable days in ICU), clinicians cannot predict with certainty which patients will survive critical illness. Therefore, it is difficult to know what length of stay is optimal for the critically ill population. From the perspective of families, some time may be needed to prepare for the death of a loved one, to make decisions that require acceptance of death as an outcome, or to travel to the bedside to support a dying family member. It is likely preferable and a better fit with patient-centered care principles to determine the right length of stay by considering patient and

family needs, values and preferences for the care rather than the healthcare system capacity to deliver critical care services (Wennberg et al., 2004).

Although we found no difference in mortality between intervention and usual care groups, there appeared to be a significant reduction in ICU days for the intervention patients in 2 of 4 studies (Schneiderman et al., 2000; Schneiderman et al., 2003). This was not surprising given these studies recruited critically ill patients including patients whose clinicians felt they were receiving futile treatment. Decisions therefore did not impact survival but rather influenced timing of death through communication with family. We know that clinician prediction of mortality is only moderately accurate (Sinuff et al., 2006) and so it is possible that life support could be withdrawn for patients who might have otherwise survived. However, in these trials this risk is low since the interventions were trialled late in the ICU stay when prognostic indicators suggested a high probability of death and the focus of the studies was on conflict resolution rather than facilitating opportunities for supportive communication or directly improving quality of decision-making. Future studies could continue to evaluate mortality rate to guard against this possibility.

Limitations

Three important limitations of this review were potentially missing trials, limited reporting of interventions, and potential risk of bias. We relied on available reports to provide descriptions of interventions and outcomes. Selective reporting bias may exist and lead to an incomplete evaluation of the intervention in our systematic review. Finally, we included only RCTs to minimize bias yet excluded studies that trialled interventions using other designs which may also contribute to an understanding of how to better achieve quality in end-of-life decision-making.

Implications for Clinical Practice

Although SDM shows promise as a way of examining and improving the decision-making process in the ICU, little is known about effective interventions to guide clinical practice supporting this process. These four studies evaluated interventions to

improve communication between healthcare professionals and patients/families when facing the decision about whether or not to use life support in the ICU. An intervention such as an ethics consultation that included essential elements of SDM was more effective than usual care with regard to resource use. Unfortunately, the studies reporting on the intervention that included most of these elements did not evaluate outcomes related to SDM (Schneiderman et al., 2000; Schneiderman et al., 2003). Other interventions to improve communication between healthcare professionals and patients/families such as structured family conferences did decrease stress, anxiety and depression in families (Lautrette et al., 2007), met information needs (Lautrette et al., 2007), and increased focus on patient preferences (Lautrette et al., 2007) without affecting patient mortality (Lautrette et al., 2007; Schneiderman et al., 2000; Schneiderman et al., 2003; SUPPORT, 1995). Given that the interventions evaluated meet some elements of SDM and impact positively on health outcomes, their implementation is warranted as an initial step towards SDM.

To enhance the process of SDM, nurses and other healthcare professionals should consider the SDM processes that occur between clinicians and families in their clinical settings with respect to the use of life support treatments in the ICU. Like the specially trained nurse in the SUPPORT study, nurses can provide patients, families and their healthcare teams with additional guidance during the iterative SDM process. However, a potential support role for nurses in the SDM process was not fully explored in the included studies. For example, nursing support for deliberation during SDM could also include: 1) making explicit that a decision is being made, 2) helping patients and families develop an understanding of the benefits and harms of options available to their relatives at the end-of-life, 3) helping patients and families reach a common understanding about how the patient's values and preferences, or those of other family members or healthcare professionals, might influence their choices about healthcare, and 4) facilitating families' deliberation with the healthcare team in ICU. By addressing these elements, the ultimate decision is more likely to be informed by patients' preferences as communicated by their family. Notwithstanding that included studies did not fully explore interprofessional roles

in the interventions trialled; each professional can play an important role in the SDM process, ultimately contributing to an integrated and cohesive approach to healthcare decision-making.

Implications for Research

This review of the research highlights the need to more thoroughly measure the implementation and effectiveness of interventions to improve communication about the decision to use life support in the ICU. Future studies would benefit from a clear and transparent framework that conceptualizes SDM beyond the patient-physician dyad and guides the healthcare team to support families in life support decisions as well as provides an approach to intervention design and evaluation. More specifically, there is a need to evaluate the effect of interventions inclusive of essential elements on SDM process and outcomes. The few intervention studies available (4 RCTs included and 18 other designs excluded) reflect the increasing interest in studying improvements in the way life support decision-making is facilitated.

Conclusion

Patients and families want to be involved in decisions about life support and it is likely that they can be better engaged in SDM. Emerging evidence to guide clinical practice suggests that having someone on the interprofessional team assigned to the role of facilitating communication will address some of the essential elements of SDM and improve health outcomes. However, to fully support the process of SDM, more comprehensive interventions are required. This systematic review contributes to a deeper understanding of the available evidence and suggests research priorities towards improving communication with patients and families about the decision to use life support in the ICU. Collaboration amongst health professionals, patients and families will be essential to ensuring that the critically ill patient's values and preferences guide decisions about their health treatments.

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Contributions of Team Members

JK conceived of the study and designed the study with support from DAF and DS. JK and EH completed the screening. JK, EH and MAM extracted data. JK, EH, MAM and DS provided support with analysis. All authors contributed to, reviewed, and accepted the final version of the manuscript.

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Chapter 3: Family Involvement in the Process of Decision-Making about Life Support in the Intensive Care Unit: A Qualitative Study

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Abstract

We explored family involvement in decisions about life support interventions in the Intensive Care Unit using a critical incident technique to focus on specific case exemplars contributed by participants. Six family members and nine healthcare professionals were interviewed. Participants described two options (life support or comfort care) and values associated with options: maintaining quality of life, surviving critical illness, minimizing pain and suffering, not being attached to machines, needing adjustment time, and judicious healthcare resource use. Barriers to involvement included not being offered alternative options; no specific trigger to initiate decision-making; dominant influence of professionals' values; and families lacking understandable information. Family members are unlikely to engage in decision-making unless professionals identify the decision and address other barriers to family involvement.

Introduction

Life support interventions are used in the care of critically ill patients in the Intensive Care Unit (ICU). Some patients do not survive and a decision to withhold or withdraw life support interventions is made prior to 50% to 90% of deaths.¹⁻⁴ Withholding refers to not initiating life support, whereas withdrawal means providing comfort care and sedation while discontinuing life support.³ Life support interventions include medications that support the heart, mechanical ventilation, oxygen, and dialysis. Discrete options, such as to initiate life support or to provide comfort care, are interventions which healthcare professionals implement after an order is written in the chart.

Proactive communication during the decision-making process seems to increase agreement between healthcare professionals and family members about using life support interventions and results in an earlier decision to provide comfort care interventions when life support is no longer consistent with the preferences of the patient.⁵⁻⁸ Guidelines for critical care professionals recommend that shared decision-making be implemented to improve the quality of end-of-life decision-making in clinical settings like ICU and emergency.^{9, 10} However, a study of 51 physician-family conferences in the ICU about end-of-life treatment decisions concluded that only 2 of these conferences met all of the criteria for shared decision-making.¹¹ These findings are consistent with studies from other clinical areas that show patients and families are not optimally involved in the decision-making process.¹²⁻¹⁶ Notwithstanding, patients and their families want to be involved in decisions about life support in the ICU. For example, in a survey of Canadian families with a seriously ill member in hospital, 81% of substitute decision-makers wanted to share in decision-making.¹⁷

Shared decision making (SDM) involves collaboration of healthcare professionals with patients and their family members during the health decision-making process.¹⁴ Family includes the surrogate decision-maker and other members so designated by the patient.¹⁸ Healthcare professionals in ICU include physicians, nurse practitioners, physician assistants, nurses, respiratory therapists, social workers, pastoral care workers,

and clinical ethicists. Therefore, given the number of stakeholders potentially involved in the decision-making process for critically ill patients, it may be helpful to conceptualize SDM beyond the physician-patient dyad to include these other healthcare professionals and family members.

The Interprofessional Shared Decision Making (IP-SDM) model describes how patients and their family members might collaborate with professionals from different disciplines to ensure an integrated and cohesive approach to the decision-making process (Figure 1).¹⁴ Although the model was validated in primary care settings, it supplies an organizing framework to build an understanding of SDM for decisions about life support interventions for critically ill patients. The model identifies key stakeholders: the patient, family member(s), and healthcare professionals (Figure 1). Patients are centrally located in the SDM process and their perspectives remain vital. During SDM, the role of healthcare professionals is to initiate the process and then support stakeholders as they identify the decision to be made, exchange information about the relative benefits and harms of the options, and elicit the patient's values and preferences. Values are an individual's judgment of the desirability / undesirability of specific elements of an option (e.g. the procedures, mode of delivery, timing, and/or duration involved in undergoing a particular option or the expected physical, emotional, and social effects).¹⁹ Deliberation among key stakeholders and across steps in SDM is essential to building a successful collaborative relationship towards the goal of reaching agreement for a higher quality health decision.¹⁴

The most common barriers to involving patients and families in SDM are described in a systematic review of 38 studies and included time constraints, lack of applicability due to patient characteristics or clinical situation.²⁰ In the validation study for the IP-SDM model, participants reiterated the importance of such barriers and added that an imbalance of power between stakeholders could be an important barrier to implementing SDM in the primary care setting.¹⁴ However, none of these studies were conducted in the ICU setting. Therefore, this study was designed to address this evidence gap by exploring family involvement in decisions about life support in the ICU. Specific

research questions were: How was the decision about life support interventions conceptualized? What were the key values used to construct a preference for the options? What roles did healthcare professionals and families have in the decision-making process? What were the barriers to an interprofessional approach to involving family members in the ICU in decision-making about life support interventions?

Methods

In this qualitative descriptive study, healthcare professionals and family members of critically ill patients in the ICU were interviewed between July 2008 and May 2009 using the Critical Incident Technique.²¹⁻²³ This technique was chosen to focus the participants' attention on events that illustrate the practical experience of their involvement in the decision-making process. We defined a critical incident as a specific case exemplar of the decision-making process about life support interventions that was contributed by the participants. To elicit critical incidents, healthcare professionals were asked to describe in detail at least two exemplars to illustrate their best and worst experience with decision-making. Family members were asked to describe at least one critical incident based on their current experience deciding about life support interventions for the patient in ICU. Participants were prompted to describe the decision-making process from the exemplar in detail (including what led to the critical incident and resulting impact), the options or alternatives that were considered, their role in the decision-making process and the roles of others involved (Appendix A). As well, participants were asked about factors which promoted or detracted from their ability to effectively involve family members in SDM.

A purposive sample of participants was recruited at the Ottawa Hospital ICU. This hospital is an 1195 bed tertiary care hospital with 65 intensive care beds providing specialized surgical, medical and trauma care at two sites and serves a population of 1.1 million in Eastern Ontario. In 2008/2009, approximately 2300 patients were admitted to the closed ICU under the care of an intensivist and an interprofessional team of physicians, nurses, respiratory therapists, social workers, pastoral care workers, and clinical ethicists.²⁴ This ICU is fairly typical of a Canadian academic teaching hospital.

Eligible participants were adults 18 yrs and older and who were able to participate in an English language interview. Family members were eligible if the patient had been in ICU more than 24 hours and had a greater than 50% probability of dying. We purposefully invited family members who were male or female spouses, adult children or siblings of either younger (closer to 18 yrs) or older (over 75 yrs) patients. Healthcare professional participants cared for patients or families in the ICU. We purposefully interviewed healthcare professionals from different disciplines on the interprofessional team but did not require them to be involved in the care of patients related to family member participants.

Data were collected during face-to-face interviews with participants, after obtaining their written consent. Interviews were audio-recorded and field notes were taken by the interviewer (JK) during and following each interview. Demographic data were collected at the end of the interview. Analysis occurred after each interview to inform subsequent interviews. Interviews were transcribed verbatim and the NVivo 8 software program was used to facilitate data management. Directed content analysis²⁵ of interview transcripts was done by the interviewer (JK) using the research questions and guided by the IP-SDM model (Figure 1).¹⁴ Directed content analysis involved reviewing transcript passages to identify critical incidents which were then grouped into categories that described the options, key values, roles in the decision-making process and barriers to involving families. Once a segment of the transcript was grouped into a category, the content was coded inductively into themes. Coded passages were reviewed and the codes were refined to ensure that coding represented the data. The coded passages were audited by another member of the team (DS) to ensure that the quotes fit the themes and to ensure that no themes or passages were missed in the coding. Discrepancies were resolved through discussion by these two members of the team to reach consensus; any disagreements were resolved with a third member of the team (IG). The study was approved by the University of Ottawa and the Ottawa Hospital Research Ethics Boards.

Results

A total of 15 individuals agreed to be interviewed (Table 1). On average, each interview lasted 50 minutes (range 22-79 minutes). The 9 healthcare professionals who participated in individual interviews had an average of 16 years experience in the ICU (range 7-25 years). Six family members of three patients admitted in ICU participated in family interviews; the patients had been in ICU for approximately one week on mechanical ventilation (range 6-28 days). The 12 interviews conveyed data around 115 critical incidents (2 - 23 per interview); each instance was selected by participants to illustrate the decision-making process about life support interventions for a critically ill patient in ICU. The following highlights the options or alternatives that were considered, their role in the decision-making process and the roles of others involved, as well as barriers to involving family members in SDM.

In this study, all patients were on life support interventions (receiving at least mechanical ventilation) and none of the participating family members perceived that they had been involved in decision-making to start mechanical ventilation or other interventions: *Actually, I don't think I've ever had to answer yes or no.* One family member described: *When she was transferred back, I had no input, no input. I was told that she's back and she's in ICU... and she's been here ever since.* As a result, families had a limited ability to describe their involvement in the decision-making process and many of the quotes describing the decision, values and barriers are from the healthcare professionals. Healthcare professionals reported that families were most frequently involved in decision-making just prior to decisions to withhold or withdraw life support and provide comfort care interventions, but less routinely in decisions to start life support interventions. This perspective is consistent with family members' accounts of their involvement.

How do professionals and families conceptualize the options?

Families were aware that the patient was receiving life support, and described it in general terms. For example, one family member explained *yesterday they had done the two hour stint of getting him off this, this machine* indicating the mechanical ventilator.

Although family members identified only the life support interventions that the patient was receiving but not alternative options, healthcare professionals identified two key options: life support and comfort care. Healthcare professionals described life support interventions using multiple technical terms (i.e. *dialysis, intubation, ventilator, BIPAP* [Bilevel Positive Airway Pressure], *vasopressor, oscillator*). However, when describing their usual conversations with families, they simplified options by using the general term *life support interventions* and described the alternative with terms like *comfort care, comfort measures, or keeping the patient comfortable*.

What values associated with options underpin the participants' preference?

Participants identified six values which influenced their preferences for whether or not to intervene with life support; three values were identified by both family members and health professionals while three values were identified only by health professionals. Both groups highly valued maintaining quality of life, surviving critical illness, and minimizing pain and suffering. Healthcare professionals reflected that family members value that patients are not attached to machines and based treatment recommendations on giving the family enough time to adapt emotionally to the patient's health situation and judicious use of healthcare resources.

With respect to maintaining quality of life upon discharge from ICU, if life support interventions were used, one family member described that *to have no energy, not be able to do puzzles, or not be able to think clearly* would be unacceptable quality of life to the patient. Another healthcare professional integrates the patient's values and describes quality of life being based on pre-admission quality of life:

If he was somebody who had end stage COPD and was sitting at home and couldn't really do anything and was just happy to sit on the porch and watch the world, I can get him back to that, I probably could.

Second, all participants valued the patient surviving the critical illness. A family member reflected on her willingness to increase the patient's chance of survival: *I signed a paper. I had to, of course, because I could see how weak he was*. One healthcare

professional described how survival influenced one family's decision: *Finally when I just said 'he can't survive this' they just kind of changed [the family's preference]; they just realized where they were at.*

The third value was minimizing pain and suffering. One healthcare professional described: *When it came to a point where it was obvious this woman was suffering daily, she could not move without pain... it was so clear to us that we could turn off the ventilator and end her suffering.* In another critical incident, a family member described: *I don't know if I can take it anymore, the pain, not in a lot of pain for a long time. I think that would be inhuman to him.*

Healthcare professionals also shared three other values that were not reported by family members. They felt that family and patient sometimes valued not being attached to machines. One healthcare professional explained:

But for some people, being hooked up, the visualization of coming into a room and seeing all the support and the machines that the patients are attached to, when they have expressed at some point, I don't want to be kept alive on machines [is not acceptable].

Healthcare professionals also valued giving families enough time to adapt emotionally to the patients' health situation. As one healthcare professional explained: *In this case they needed more time before she died, since the diagnosis was new, they were comfortable with the decision. This kind of gave them another couple of days, a few weeks* Finally, healthcare professionals also valued the judicious use of healthcare resources. One professional described: *We were terribly understaffed. The medical staff decision was, it's clear; this patient was on their deathbed for two, three days, that's enough.* A different healthcare professional reflected on another incident:

She eventually did arrest one night but that was about four months later. ...It is difficult to keep your own emotions in check because you feel terrible about

keeping someone on life support for that length of time. And there are issues of distributive justice, having a patient we couldn't accept for transfer.

What roles did participants have in the decision-making process?

Participants identified three roles in the decision-making process: leader, support and advocate. Both family members and healthcare professionals reported that the senior physicians in ICU took on a leadership role in which they initiated the decision process, identified the options and made the decision. One healthcare professional asserted that as an intensivist *you're the most responsible physician and that discussion should be initiated there* and another added that *in these decisions the physician is the person with the authority to decide*. Another physician felt that it was expected as part of his/her role: *Family members are looking for your expertise and your decision... Sometimes you get the sense that when you are making decisions based on your best medical knowledge that they are relieved not to have to make that decision. They would rather that somebody who had special knowledge or expertise make that decision.*

Both family members and healthcare professionals identified that all healthcare professionals in ICU took on a support role during the decision-making process. The support role involved helping other professionals and family members describe their perspectives, mediating when communication issues arose, providing emotional support to colleagues and families, assessing families' understanding, and clarifying information for families. One nurse described support in the following way: *I think nurses can get that information to the family to help them, and I think that often we're that "go between" between the family and the physician.*

Some healthcare professionals felt that family members acted as patient advocates. Family members helped the healthcare team understand the patient's perspective by sharing what was important to the patient and relevant personal circumstances, helping the team construct the patient's preferences around the decision, and communicating the patient's previously expressed preference for life support interventions. When family members were not included in decision-making, other

healthcare professionals like nurses, clinical ethicists, or social workers, advocated for the patient and family to the team: *We get the family conference organized to discuss issues or advocate for the family to the physician to get them to come and speak, make that initial call ask again, follow it up in rounds and things like that.* In contrast, other healthcare professionals felt that family members' role as advocate was limited to accepting their decision to withhold or withdraw life support on behalf of the patient and explained:

I can't just go in the room and pull a plug. You do need the family's acceptance of what is going to happen. Not necessarily decide what's going to happen, but they have to accept what you are telling them.

What were the barriers to involving families in SDM?

The critical incidents described by family members and healthcare professionals demonstrated 14 barriers which interfered with involving family members in the decision-making process. Participants felt that these needed to be minimized to successfully engage in SDM. Table 2 lists the barriers at each element of the IP-SDM model with supporting quotes. Barriers to initiating the decision included: not including alternative options, desire to avoid burdening family, no specific trigger to begin the process of decision-making and not being emotionally ready to engage in the process. For example, healthcare professionals reported that physicians usually make the decision and present the option as a plan of care to the patient or family member(s). Some healthcare professionals felt that requiring families to make a decision about life support interventions, especially one to withhold or withdraw interventions, was cruel and unnecessarily burdensome for families. These healthcare professional participants negatively viewed SDM as presenting families with a dizzying array of options and giving the family the 'freedom' to make a choice while inappropriately abdicating their professional responsibility to guide families or make recommendations. Although some healthcare professionals agreed that families could be involved earlier in the process to consider alternatives when they were still salient, there was no trigger for initiating SDM with families. Healthcare professionals agreed that it was important to ascertain the

families' readiness to engage in SDM about life support interventions and described having supported families to bring about this readiness (e.g. by listening to their concerns and providing emotional and spiritual support). Some critical incidents described cases where the team avoided involving families because healthcare professionals were not ready to consider alternative options like comfort care.

Barriers to effective information exchange were identified from the family perspective and included not receiving understandable information, not knowing what questions to ask and receiving inconsistent messages from the team (Table 2). Healthcare professionals noted that not receiving understandable information or receiving inconsistent information from various team members were barriers to effectively involving families. One family member admitted that his understanding of the treatment that the patient was receiving was poor and did not know what questions to ask.

Two clear barriers to eliciting values were the dominant influence of healthcare professionals' values and different values among family members (Table 2). Most healthcare professionals agreed that they could not make the decision about life support until they knew the patient's values. Some realized that their assessment of patients' state of health and how it related to future quality of life, possibility of survival and perceived minimizing pain and suffering were not always concordant with patient and family's assessment of these same elements. The dominant influence of healthcare professionals' values was evident in both their deciding on the 'appropriate' treatment based on their assessment of likelihood of morbidity and mortality, and by their descriptions of conversations sometimes framed to convince family to consent to the pre-determined option. Another barrier to involving family members in SDM was that different values among family members sometimes created conflict.

Healthcare professionals described two barriers to involving families in making the decision: difficulty reaching agreement and being unclear about the patient's values and preference (Table 2). All healthcare professionals recalled examples of difficulty reaching agreement about life support interventions because of different perspectives held

by healthcare professionals, family members, or the patient that could not be resolved. In some cases the patient on life support interventions died before a decision was made; but in other cases the patient received life support for prolonged periods while key stakeholders deliberated about the best course of action. Healthcare professionals expressed concern about involving family members who had not previously discussed life support interventions with the patient or who were unsure about the patient's preference for life support interventions.

Asymmetry of power, lack of therapeutic relationships with family and lack of collaborative team relationships were identified as barriers to interprofessional collaboration involving family members (Table 2). Asymmetry of power was evident in some healthcare professionals' reflections about the limited value of the family member's perspective and descriptions of the consent process with family members. Family members discussed feeling less knowledgeable and relied on the healthcare team's expertise. Family members were also reluctant to critique the care the patient was receiving and expressed worry that the healthcare team might abandon the patient leaving them in a situation where family couldn't provide the needed care (e.g. life support interventions). In contrast, healthcare professionals controlled the flow of information about the patient's condition and could implement treatments. Healthcare professionals felt that a difficult relationship with family members was often a result of poor communication. Healthcare professionals reflected on the challenge of needing to initiate relationships with family members under tense circumstances when a patient was critically ill and the family distressed. Finally, the lack of collaborative relationships among healthcare professionals was evident from participant statements about how poor relationships and minimal interdependency amongst professionals contributed to lack of integrated and cohesive care.

Discussion

This study improves our understanding of the decision-making process about life support interventions in the ICU by describing the options, the key values influencing preferences for different options, the roles of healthcare professionals and families in

SDM, and barriers to engaging family members in these decisions. Family member participants did not perceive that they had been involved in the decision about life support interventions and therefore couldn't articulate alternatives to life support interventions. Healthcare professionals identified two options in the decision about life support interventions: to use life support interventions for critically ill patients or to focus on comfort care. The values that influenced preference for life support interventions or comfort care included maintaining quality of life, surviving critical illness, minimizing pain and suffering, not being attached to machines, giving the family enough time to adapt emotionally to the patient's health situation and the judicious use of healthcare resources. Three roles in SDM were the physician role as leader, healthcare professionals' support role, and the patient advocate role of the family. Despite a perception that family had a clear role, family members were unlikely to become engaged without healthcare professionals making explicit the decision to be made and minimizing other barriers across the decision-making process.

A key barrier to involving family is 'not presenting alternative options'

Although patients had received life support interventions for 6 to 28 days at the time of the interview, the decision to initiate life support intervention or the decision to consider current options had not been made explicit with families. This is consistent with other studies where alternative options are rarely discussed with patients or their family members in an explicit decision-making process.²⁶⁻³⁰ When family members are not made aware of alternative options, healthcare professionals may be missing an important opportunity to involve families in deliberation. Patients and their families need to know the options that are available to them in order to weigh one option relative to alternatives and provide informed consent^{31, 32}; this is a key element of an SDM approach.

Patient centered care requires that patient values influence decisions

Decisions that are informed and based on the values of individual patients are of higher quality.³³ While patient perspectives are difficult or impossible to elicit in the ICU (e.g. due to treatments such as mechanical ventilation), it is possible to incorporate how the patient might value options with family input. It is generally accepted that family

(rather than healthcare professionals) are the next best proxy to represent patient preferences.^{9, 34-36} Indeed, in many of the critical incidents, healthcare professionals agreed that family could best represent the perspectives of the patient in their role as patient advocates. However, while healthcare professionals reflected that the best option for any patient depends on their individual values, their own values as health professionals appeared to strongly influence the decision. Other studies have also shown that values of healthcare professionals have a greater role in life support decisions compared to the values of patients^{37, 38} and as a result sometimes there is no significant association between patient preference and life-sustaining treatment use.³⁹ Healthcare professionals must therefore collaborate with patients and their families to identify individual patient preferences to achieve patient centered care.⁴⁰

SDM calls for a renewed focus on deliberation

Healthcare professionals in our study perceived that sharing equal responsibility for making decisions about life support interventions for critically ill patients with families was an excessive burden for the families. The distinction between the process of deliberation and the decision taken is discussed in detail by Elwyn and Miron Shatz.⁴¹ They point out that current research focuses on outcomes of patient involvement (i.e. the decision) and emphasize that an important but possibly neglected indicator of decision-quality is having the opportunity for patients to deliberate effectively prior to making the decision.⁴¹ SDM calls for a renewed focus on deliberation which may ease the perceived burden that choice places on families in ICU. Proactive support for families during deliberation about life support interventions has been shown to improve communication and understanding between the family and team, and facilitate end-of-life decision-making.^{6, 42} Structured family conferences reduced the burden on bereavement even when provided after the decision was made to withdraw life support interventions.⁴³ Indeed, whether involving patients and families in the moment of making the decision is sufficient or even required for SDM remains an empiric question. However, if provided earlier, decision support could contribute to the families' ability to re-examine the options as the context evolves. As well, families' preferred involvement in decision-making can

evolve over time;^{44, 45} therefore, it is necessary to assess their evolving preferences and involve families in making the decision to the extent desired. Regardless of who makes the decision, the goal remains to reach an informed decision that is based on the patient's values.¹⁴

IP-SDM model can be used to identify modifiable barriers

Although the IP-SDM model was developed and validated in primary care,¹⁴ it appears to fit well within the ICU context. Nevertheless, this study adds three important considerations when the model is applied in ICU: 1) the advocate role held by family; 2) initiation of the decision-making process seems to be affected by the emotional readiness of all stakeholders; and 3) adjustment to the deliberation process may be needed to ensure that patient and family values are elicited in view of the potentially dominant influence of healthcare professionals' own values. Roles identified in our study were easily mapped onto the roles descriptions in the IP-SDM conceptual model. For example, the decision coach role was consistent with the support role held by many healthcare professionals in our study and the initiator role was consistent with the intensivist's leadership role. Our study further defines the family members' role as one of advocate for the patient in ICU. The advocate role is consistent with the role of substitute or surrogate decision-maker described in current legislation (e.g. statutes in Ontario³¹ or Washington State³²).

Emotional readiness to initiate the decision-making process was an issue for both the family members and the healthcare professionals in our study. Similarly, other studies have suggested that families needed time to prepare for transitions to withdrawing life support^{29, 46} and needed emotional support to prepare them for engagement in decision-making in ICU.⁴⁷ Research in the experience of healthcare professionals involved in withholding and withdrawing life support suggested that healthcare professionals need to come to terms with the decision and if they did not, suffered moral distress or dissonance.^{48, 49} Further exploration is needed to determine how emotional readiness contributes to progressing in the decision-making process and its impact on deliberation during SDM for life support decisions.

Given the potentially dominant influence of healthcare professionals' own values, interventions may be required to make the patient's values explicit in the deliberation process. Interventions to clarify and communicate patients' values are incorporated in patient decision aids and include: 1) describing the options in detail, 2) providing examples of how others value the options, 3) rating or trade off exercises, and 4) suggesting ways to communicate values with others¹⁹. Patient decision aids can be embedded in the processes of care because they are designed to be completed by patient/family either in preparation for discussion or during the consultation with a member of the healthcare team. Some decision aid trials have included a decision coach (with or without a decision aid) who is non-directive but supportive in the decision-making process.⁵⁰ Research groups have pilot-tested decision aids for similar contexts, for example an aid to assist patients with end stage COPD in the community to take decisions about mechanical ventilation in advance of respiratory failure,^{51, 52} a video decision aid to facilitate end-of-life discussions with cancer patients,^{53, 54} and a paper based decision aid to help seriously ill hospitalized patients decide if they want to be resuscitated if their heart stops.⁵⁵ However, there is a need for tools that could be used to support patients and families in acute care and ICU settings when they are faced with decisions about life support interventions; tools that could help them actively engage in SDM with their healthcare teams.

Study strengths and limitations

Perspectives of healthcare professionals from many disciplines and family members enhance our understanding and highlight the complexity of end-of-life decision-making in the ICU. Through these interviews, we were able to identify 115 critical incidents which provided a rich description of family involvement in SDM. Based on other critical incident technique studies, Flanagan suggested that researchers adequately captured and described the incidences being explored when adding 100 critical incidents to the sample contributed only two or three more themes to the analysis.²² In our study, the first two participant interviews contributed 19 critical incidents and all but two themes to the analysis; the remaining 10 participants described a further 96 critical

incidents contributing two additional themes to the description of barriers. No new themes were added during the analysis of the last five interviews. We felt that the data categories had reached saturation since we had interviewed families and healthcare professionals from each professional group working in this ICU.

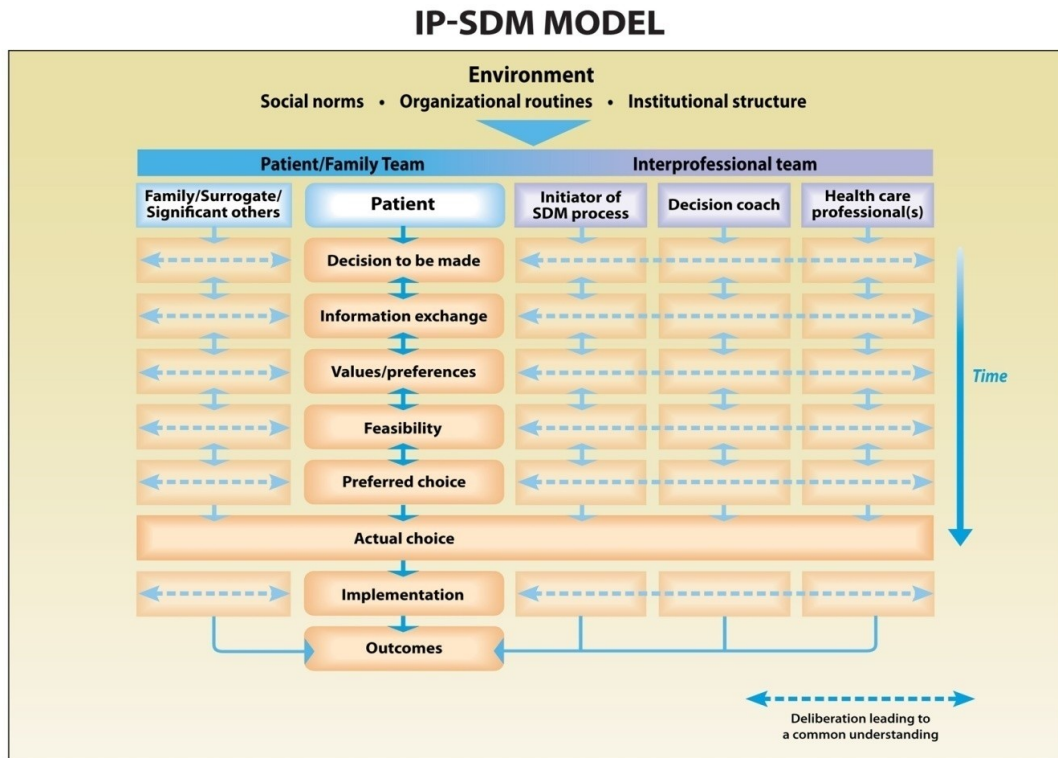
However, the values associated with options reported in the study may not represent the full range of values that influence the decision-making process about life support interventions in the ICU. In particular, two limiting factors exist: 1) the values reported by family members may be more similar within their three family units; and 2) family members were limited in their ability to report on the desirability / undesirability of specific elements of the options (values) since they did not perceive that they had been involved in the decision about life support interventions and couldn't articulate alternatives to life support interventions. Furthermore, we were unable to identify or recruit family members who were likely to have been more involved in this particular ICU and therefore additional family interviews may not have yielded new themes. Further research should be conducted in situations where family members are explicitly involved in shared decision-making about life support interventions to determine if new themes arise.

Participants shared extremely detailed stories of their experiences which increases confidence in the accuracy of their account.²² Responsiveness to participant perspective and reflexivity during interviewing enhanced the credibility of the findings. Credibility of findings was also enhanced by having one member of the research team conduct the interviews and code all of the data by transcribing audio recorded interviews and having another member of the research team audit the coding results. Finally, descriptions of the participants and the setting as well as quotes from the participants can facilitate transferability of the findings to other clinical settings.⁵⁶

Implications and conclusions

SDM is a process of arriving at a decision which includes but is not limited to the moment of choosing an option. There are clear roles for family members and healthcare professionals in the process of deciding about life support interventions in the ICU, which are consistent with an SDM approach. However, family could be better involved in SDM if the decision was made explicit and other barriers were minimized. There was a commitment on the part of professionals interviewed to include families, to establish relationships early in the ICU stay, and to try to reduce family members' distress around decision-making in ICU. This task was deemed possible if it was undertaken by an interprofessional team poised to collaborate among themselves and with family members, had clear roles, and made explicit the decision-making process. By having a better understanding of barriers to family involvement in decision-making, interventions can be designed to overcome these barriers and move closer to ensuring higher quality decisions about use (or discontinuation) of life support interventions.

Figure 1 The Interprofessional Shared Decision Making (IP-SDM) Model



Note. From “Validating a conceptual model for an interprofessional approach to shared decision-making: A mixed methods study” by F. Legare, D. Stacey, S. Gagnon and colleagues, 2010, *Journal of Evaluation in Clinical Practice*, p. 4. Copyright 2010 by Blackwell Publishing Ltd (Wiley). Reprinted with permission.

Table 1 Characteristics of participants

Demographic	Healthcare professionals (n = 9)	Family members (n = 6)
Age [median (range)]	41 years; 33 – 54 years	50 years; 24 – 82 years
Sex	4 Male	1 Male
	5 Female	5 Female
Marital Status	1 Single	2 Single
	8 Married	4 Married
Education	2 University	1 College
	4 Masters	5 University
	3 Specialty training	
Relationship to patient	Doctor, Nurse, Respiratory therapist, Social Worker, Spiritual Care Worker, Clinical Ethicist	Spouse, Mother, Sister, Daughter
Religion	3 Christian	3 Christian
	1 Secular	3 Muslim
	5 Not declared	

Table 2 Barriers to Shared Decision Making in Intensive Care Unit

	Barriers	Exemplary Quotes (Family (F) or Healthcare professional (H) perspective)
Decision to be made	Not offering alternative options	<i>The options were to continue his existence with the support of a ventilator, with chronic dialysis; no one was talking about withdrawing treatment. (H)</i> <i>There was no choice. But it was a very fast decision. (F)</i>
	Desire to avoid burdening family	<i>The family - it's totally cruel they're dealing with what's about to happen, which is the death of a loved one, and you're putting whether or not that happens, on them. (H)</i> <i>One of the things that's so stressful about being here is that you don't know if people are telling you the truth, right. So your family member is deathly ill and you don't want people to placate you. (F)</i>
	No specific trigger for the process	<i>Sometimes a physician group will hold off in discussing end-of-life ... or not giving them the whole picture, which prolongs that family's decision-making process.(H)</i>
	Not being emotionally ready to engage in the process	<i>We invest so much in those patients and in the families that, that sometimes we don't want to give up ..., when the patient finally says 'hey I've had enough' or the family says 'hey, we've had enough and we think [the patient] would have had enough', we're often not ready and maybe we should be. (H)</i> <i>Our challenge is how do we bring the family to the point where we are? ...we can tell people things and we can teach them things, but it's not what they know; it is what they accept in their hearts. (H)</i>
Information exchange	Not having understandable information	<i>The family doesn't realize sometimes that the Levophed has been cranked up to 30. (H)</i> <i>And in a time of stress, no matter what, you may have said ten points and they've only got two... (H)</i>
	Not knowing what questions to ask	<i>Because I, I really don't know what questions to ask. (F)</i>
	Inconsistent messages from team	<i>One person who would give the family hope, when everyone else has painted the picture the way it is, it really changes things. I think everybody loses credibility and the family is just sort of left on their own - to sort of wander aimlessly not knowing. (H)</i>

Values	Dominant influence of professionals' values	<i>An operation where things are going to rapidly reverse would be appropriate even in someone who is perhaps a DNR, whereas an operation that has a low probability of recovery and a high risk of morbidity and mortality may not be appropriate in that patient. (H)</i>
	Different values among family members driving preferences	<i>So, this is a family who started at ground zero, completely opposed, opposing views. So, then if it is not their decision, like if you just completely take it away, nobody can be mad at each other, and they are still going to be a close knit family.(H)</i>
Choice	Difficulty reaching agreement	<i>Everybody was trying as hard as they could to persuade this patient that they wanted him to continue and they were hoping he would change his mind. (H)</i>
	Being unclear about patient wishes	<i>The worst kinds of decisions are the kind where family members are conflicted amongst themselves. The patient has not expressed clearly what they would have wanted in this kind of event, sudden traumatic injury. (H)</i>
Environment		<i>[Family members'] decisions are going to be emotional decisions, whereas ours are going to be informed and sort of knowledgeable decisions. (H)</i>
	Asymmetry of power	<i>Nine times out of ten at a family meeting we back off, and we bring social workers in, and we bring the priest in, we bring palliation in, um, and things like that. Behind their back. I mean, sometimes we tell them, that we're going to do this, but then other times we just initiate this sort of support network that's there and um, we sort of start to cajole them. (H)</i>
	Lack of therapeutic relationship with family	<i>I find if you leave that family in the dark, they get angry and anxious and ... they are challenging the nurse and challenging the team and they're mad H)</i>
		<i>There is a historical tendency for physicians not to include the nursing staff in decision-making. (H)</i>
	Lack of interprofessional collaboration	<i>The doctor that is coming on, if they are a team member, will listen to what has happened and hopefully understand the process and the direction that we've been going... But then there is the other 20 percent that either come in and say 'what are we doing this for, pull the plug', or they will say 'hey, let's try this, this and this'. Well, we say, we've tried that already. 'Well, let's do it again, only this time we'll do it a little different'.(H)</i>

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Chapter 4: Field Testing a Patient Decision Aid to Engage Families in Decision Making about Life Support in the Intensive Care Unit

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Abstract

Background

Field testing is a component of International Patient Decision Aids Standards (IPDAS) for development of patient decision aids (DA). The purpose was to evaluate the ability to operationalize the IPDAS criteria in the context of developing and field testing a novel DA for families facing decisions about life support for their relative in the Intensive Care Unit (ICU).

Methods

Field testing used 5 criteria identified by IPDAS: a) feasibility, b) acceptability, c) balanced presentation of information, d) clarity, and e) potential to have the desired impact without adverse consequences.

Results

Nine family members and five healthcare professionals of eight index patients were recruited. The DA was feasible to use with family members facing the decision in ICU. All 11 who rated the DA found most or everything in the DA clear and would recommend to others, 8 agreed it had the right amount of information, 10 found it helpful, 8 very good or excellent, 9 completely balanced. The DA has the potential to improve knowledge, clarify patient and family member's values for the options without appearing to augment family members' level of distress.

Conclusions

IPDAS criteria that were operationalized during the field testing informed development by demonstrating that the DA 1) was feasible to use with patients/ families facing the decision and healthcare professionals who provide support during decision-making, and 2) was acceptable to users, 3) had the potential to do what was intended, and 4) did not seem to present adverse consequences to users. An enhanced delivery strategy for healthcare professionals is needed for future evaluation of effectiveness.

Background

Although patients and their families want to be involved in decision-making [1], they are seldom presented with alternatives to the use of life support in the Intensive Care Unit (ICU) [2]. Interventions that have incorporated elements of shared decision-making in the ICU setting have improved communication with families and resulted in decreased stress, anxiety and depression in families, met family's information needs, and increased focus on patient preferences [3], without adversely affecting patient mortality [3-6] (Chapter 2). Barriers to involving patients and families in the decision about life support included not offering an alternative option, families lacking understandable information and not knowing what to ask, and the dominant influence of professionals' values (Chapter 3). Clearly patients and families in ICU will require additional support to overcome these barriers.

The implementation of shared decision-making in other healthcare settings offers some insight about how to overcome such barriers. Shared decision-making (SDM) is defined as a collaboration by healthcare professionals with patients and their family members to ensure an integrated and cohesive approach to the process of making health decisions [7,8]. A systematic review of interventions for improving the adoption of SDM by healthcare professionals showed that educational meetings, receiving performance feedback, educational materials, and patient decision aids (DAs) may be helpful to facilitate an SDM approach [9]. DAs are evidence-based resources designed to present decisions in a way that is accessible to patients and families. They provide information on the alternative options along with features of the options including both benefits and harms [10,11]. DAs improve knowledge about the options and their outcomes, increase accurate risk perception, result in a better match between values and choices, and reduce decisional conflict [12]. DAs have been integrated in some clinical settings with the help of a summary used to communicate the individual's decision needs to their healthcare team [13]. In addition to the use of a DA, involvement of family members in SDM can be reinforced by a member of the healthcare team acting as a decision coach [14]. A decision coach provides individualized, non-directive support to prepare family members

for SDM with their healthcare team [15]. When DAs are used with coaching in contexts other than ICU, patients had improved satisfaction with the decision-making process relative to the DA alone [16,17], lowered healthcare costs [17], and improved knowledge relative to usual care [18]. Therefore, in order to facilitate an SDM approach, a novel DA was developed using International Patient Decision Aid Standards (IPDAS) [10] to assist family members facing decisions about life support for a relative in the ICU.

IPDAS identifies field testing with users as part of the process of DA development [10]. In particular, IPDAS specifies four criteria related to field testing a DA: 1) field test with users (people facing the decision and professionals who counsel them), and determine 2) acceptability to users, 3) whether people who are undecided think option presentation is balanced, 4) whether the DA is understood by users with limited reading skills [10]. IPDAS criteria are based on consensus among over 100 researchers, patients, practitioners and policy makers from 14 countries, yet there is little evidence underpinning these 4 field testing criteria and little direction on operationalizing them [19]. In a background document, IPDAS collaboration defined field testing further and further included feasibility and potential to have the desired impact [19]. A broader set of IPDAS criteria for evaluating the ‘desired impact’ are that DAs should help users 1) recognize a decision needs to be made, 2) know the options and their features, 3) understand that values affect their decision, 4) be clear about option features that matter most, 5) discuss values with their practitioner, 6) become involved in preferred ways, and 7) improve the match between the chosen option and the features that matter most to the informed patient [10]. Other literature suggested field testing was useful for spotting interaction problems with related system processes or users [20] and that field testing should balance the risks of exposing participants to a novel and unproven intervention with the need to monitor that the intervention seems to do what was intended [21,22].

Therefore, the purpose of the study was to evaluate the ability of the IPDAS field testing criteria to be successfully operationalized during the development of a novel DA designed to facilitate SDM with family members facing decisions about life support for a relative in the ICU. Given the sensitivity of the decision regarding life support for

critically ill patients in the ICU, the need for field testing prior to evaluating the effectiveness of the DA was determined to be very high. Findings contribute to what is known about field testing as part of the process of DA development.

Methods

A field test of the DA was guided by IPDAS criteria and collected both qualitative and quantitative data (see Table 1 for data mapped onto criteria for field testing). The field test was approved by the University of Ottawa and the Ottawa Hospital Research Ethics Boards.

Participants and Setting

Eligible participants were 1) family members and healthcare professionals of the same ICU patient (index patient) described by their attending physician as having a greater than 50% probability of dying after 24 hours in ICU, 2) willing to participate in a discussion about life support, and 3) able to read English. This ICU was situated within an 1195 bed tertiary care hospital in Canada with 65 intensive care beds providing specialized medical, surgical, and trauma care. Patients are cared for by an interprofessional team of intensivists and resident physicians, nurses, respiratory therapists, social workers, pastoral care workers, and a clinical ethicist. The hospital serves a population of 1.1 million and the ICU mortality rate was 23% (i.e. in 2008 and 2009, unpublished data).

The Patient Decision Aid Intervention

The DA “*Understanding the options: Planning for a family member’s care during their critical illness*”, available <http://decisionaid.ohri.ca/AZsumm.php?ID=1388>, was developed to help family members become more actively involved in the decision-making process about life support for their critically ill relative admitted to the ICU (Appendix B). Guided by the Ottawa Decision Support Framework [23], the Interprofessional Shared Decision Making Model [8] and the IPDAS content criteria [10], the DA was designed to overcome identified barriers to family involvement (Chapter 3). The DA is written in plain language for a lay audience at a Flesch-Kincaid grade 8

reading level [24]. Introducing two options, life support and comfort care, family members are guided to: 1) describe their relative's health situation before coming to ICU and current situation, 2) clarify values associated with each of the options, 3) consider opinions of those involved in the decision, and 4) assess their decision support needs. Responses to questions are used to create a one page summary (Appendix C). Prior to field testing, the DA was reviewed by 4 decision support experts, 25 healthcare professionals from the Canadian Researchers at End-of-Life Network (CARENET), 3 plain language editors, and 10 adults from the general public. These reviewers provided feedback about the layout, flow, language, and overall content, which informed revisions to the final version of the guide used in this field test. For a more detailed description of DA development, see Appendix D.

Procedure

The ICU healthcare team identified eligible families for the study. Once a family member consented to participate, relevant healthcare professionals were invited to participate (Appendix E). After signing the consent form, participants were given the baseline questionnaire.

Family members were then given a copy of the DA and coached as needed through the process of completing the DA by a critical care nurse: either the bedside nurse or a member of the research team with expertise in critical care and decision coaching (JK, CF) (Appendix F). If the bedside nurse was willing to provide coaching, a brief one to one training session on how to use the DA with families was provided by the research assistant (CF). The decision coach assessed/discussed family members' decision-making needs, provided information using the DA, assessed understanding, helped family member(s) clarify their preferences, guided family members in deliberation, communication, and accessing support for SDM; and monitored/facilitated progress in decision-making.

Once the DA was completed by each family member, a one page summary of the DA was given to the family member and the ICU healthcare team to prepare for the

family meeting. Family meetings often occur in this ICU and can be requested by either families or the healthcare team, as needed. Meetings held with participating families were observed and audio recorded (JK, CF). After completing the DA and, if relevant, meeting with the ICU team, participants were given the post questionnaire and had a follow up interview (JK, CF).

Outcomes

Field test outcomes were based on the following IPDAS criteria: a) feasibility of using the DA with families and ICU healthcare professionals, b) acceptability, c) balance of option presentation, d) understanding of information in the DA, and e) potential to have the desired impact without adverse consequences (Table 1). To measure these outcomes, 6 instruments were used: 1) Acceptability Survey [25,26], 2) Family Meeting Observation Checklist, 3) Third observer OPTION instrument [27,28], 4) Preparation for Decision Making Scale [29,30], 5) Dyadic OPTION instrument [31], and 6) Impact of Event Scale [32] (Appendix G).

The Acceptability survey included 10 validated questions about the use of the DA, amount of information, the length, the clarity, balance in presentation, willingness to recommend to others, and overall suitability for SDM [25,26]. The survey asked participants to select a statement that best responds to a question (i.e. the question “how balanced was the information presented in the DA? could be answered “a little slanted towards life support treatments”). Each item was interpreted individually. The survey has been validated when evaluating SDM programs at the Foundation for Informed Medical Decision Making.

Two checklists were used to describe the decision-making process which occurred during family meetings: the Family Meeting Observation Checklist and the Observing Patient Involvement (OPTION) instrument [27,28]. The researchers (JK, CF) noted whether 20 distinct components of the DA were addressed during the family meeting using the Family Meeting Observation Checklist developed for this field test. The third observer OPTION instrument was developed to evaluate SDM in the primary care setting

[27]. Observers selected a response from the five point scale ranging from ‘the behaviour is not observed’ to ‘observed and executed to a high standard’. The total summed score ranged from 0 to 48 with higher scores indicating greater competency in SDM [27,28]. Increased patient involvement was observed in primary care encounters after a SDM skills workshop (12.9 point increase, 95% CI 10-15.8, $p < 0.001$) and the reliability of this scale was 0.66 [27].

Family members and healthcare professionals reported their perception of how well the DA prepared family members to communicate with others about decision-making using the Preparation for Decision-making Scale [29,30,33]. The scale consisted of 10 items with a five point scale ranging from “not at all” to “a great deal” [29,30,33]. The total summed score ranged from 10 to 50 with higher total scores reflecting greater preparation for SDM. The scale discriminated between different decision support interventions with an effect size of 1.8. The total test reliability was 0.94 [29,30,33].

Family members and healthcare professionals reported their perceived involvement in the decision-making process using the self-reported dyadic version of the OPTION scale [31]. The dyadic OPTION elicited participants’ agreement from strongly disagree to strongly agree with statements characterizing their involvement in SDM [31]. The total summed score ranged from 12 to 48 with higher scores reflecting greater perceived involvement. The scale discriminated between primary care encounters though patients gave significantly higher ratings than clinicians [34].

Family members’ distress regarding the patient’s critical illness and ICU stay was assessed using the Impact of Event Scale (IES) before and after the DA intervention. The IES elicited family member’s psychological distress associated with a specific life event [32]. The total summed score ranged from 0 to 75 with scores less than 8 indicating subclinical stress, scores 9 to 25 indicating mild to moderate degree of stress, and scores greater than 26 indicating clinically significant distress with moderate or severe impact [35]. The test-retest reliability scores were 0.87 for total stress score, 0.89 for intrusion sub-scale, and 0.79 for the avoidance sub-scale [32]. Women considering

chemoprevention for breast cancer scored lower distress after using a DA compared to a usual care control group (21 versus 26, $p = 0.02$) [36]. The IES discriminated between relatives of patients in ICU who received proactive communication and a brochure on bereavement and those who did not (27 versus 39, $p=0.02$) [3].

Data Analysis

Quantitative data were coded and entered in Microsoft Excel (version 2007); medians and ranges were used to describe the small sample rather than make inferences to a population. The extent to which results met the identified criteria is described. Field notes were coded and entered into the excel database to facilitate data management. Directed content analysis [37] of field notes was done by the principal investigator (JK) and involved grouping field note passages into categories that described the semi-structured interview questions and research questions. Two members of the research team independently rated SDM elements that occurred in the audio-recorded family conferences using the OPTION instrument and the Family Meeting Observation Checklist (JK and CF or SG). The quantitative and qualitative data were triangulated in the presentation of findings.

We determined that the DA successfully met the criteria for field testing if: 1) the DA was used by at least 66% of family members who consented to participate, 2) identified barriers to use were resolvable, 3) the DA was used by at least 66% of users during family meeting, 4) the DA was acceptable to at least 66% of users, 5) there was a perception of balanced presentation by at least 66% of users, 6) the DA was understood by at least 66% users; 7) at least 66% families experienced the desired impact (e.g., recognized that a decision needed to be made, knew options and their features, understood that values affect the decision, were clear about option features that matter most, discussed values with their practitioner, became involved in preferred ways, experienced a match between the chosen option and the features that matter most to the informed patient); and 8) at least 66% families did not experience an increase in psychological distress (Table 1). Given that we were unable to identify an indicator of success for field testing, the research team agreed upon the target of $\geq 66\%$ because it was

more than a simple majority (i.e. >50%) without being too stringent. Furthermore, criteria that did not achieve 66% signaled the need to consider revisions to the intervention and/or its delivery.

Results

From February to May 2010, 40 eligible patients and families were identified and 19 family members (47.5%) were successfully contacted (Figure 1). Of the 19 family members contacted, 10 declined (6 were too overwhelmed, 4 felt they did not need decision support). Of 14 eligible healthcare professionals approached, 9 declined (8 were too busy with patient care, 1 felt that the study was overly burdensome).

A total of 14 participants were recruited related to 8 index patients: 9 family members and 5 healthcare professionals (Figure 1, Table 2). In the week prior to admission to ICU, patients' health ranged from poor to excellent. Most family members were the legal surrogate decision-maker for the incapacitated patient. Healthcare professionals were nurses or physicians with two to thirty years experience in ICU. All participants agreed that families should be involved in the decision and five family members and four healthcare professionals felt that the physician and family should share responsibility for the decision about life support in ICU.

Eleven participants provided data after reviewing the DA (Figure 1). Of 9 family members, 7 provided data after the intervention. One family declined to participate after reading the DA explaining:

I can't put a mark in it [indicating the values clarification exercise]. I mean, I know what I want: I want him to try everything, to live. I know he doesn't want all this but I am just not ready to let him give up.

Another patient died shortly after family completed the DA and so data collection was not pursued. Of five healthcare professionals, one healthcare professional did not respond. Of eight index patient cases, four did not have family meetings: three families did not request such a meeting and one family wanted a meeting however the team

decided it wasn't necessary because the patient was improving. Of four family meetings held during the field test, one family declined to have their family meeting observed and three were observed.

Feasibility: Patient Decision Aid Use

Of nine family members, eight (89%) completed the DA either independently (n=7) or with other family members (n=1) (Table 3). All family members had support from a decision coach and the amount of support provided by the coach depended on the family members' needs. For example, for two families, the coach stayed in the room and provided step by step individual guidance. For other families, the coach remained available and responded to questions such as *I'm not sure if he has an infection, how can I tell? Can we discuss values as a group and decide together what to answer in this section? How do I know if this value is a 4 or a 5 - does it matter?* Families were able to answer or generate questions for the healthcare team when completing the DA. The decision summary was generated and shared with the healthcare team for all eight completed DAs; three family members also used the decision summary report to discuss the decision with other family members. In the case where the family's request for a meeting was declined by the healthcare team, the participating family member discussed the decision with the patient and other family members. When their relative was readmitted to ICU three days later, the family advocated for the patient's preference for comfort care reflected in their DA. One barrier to the use of the DA was identified when one family member was unable to complete the DA because she was not emotionally ready to integrate patient values and preferences into the decision.

All five participating healthcare professionals reviewed the DA (Table 3). Of eight nurses caring for the index patients, six declined to provide decision coaching to families because they were too busy with patient care and one felt unprepared. The critical care nurse who agreed to provide decision coaching was a recent graduate from a University where decision coaching is integrated in the curriculum [38]. The other family members were coached by a critical care nurse from the research team. Of four healthcare

professionals who provided data after the intervention, three had reviewed the decision summary report and one indicated:

I think it would be nice if I looked at the decision aid [summary form] before I go into a family meeting. It looks as though it would take me five minutes to do that. Then I can sort of tailor my language to their language.

Feasibility: Use During Family Meeting

During each of the 3 observed family meetings, a range of 8 to 20 elements of the DA were discussed; however no participants referred to the DA or summary report during the meeting (Table 4). Total OPTION scores ranged from 9 to 40 indicating considerable variation in the extent to which family members were involved in SDM about life support.

Acceptability

Seven family members and four healthcare professionals provided data about the acceptability of the DA intervention (Table 5). Of these 11 participants, 8 felt that the DA contained about the right amount of information. All 11 gave it an overall rating of “good” or better, and would probably or definitely recommend it to others. Ten rated the DA as helpful. Of seven family members, six felt that the timing of the DA was appropriate to examine life support options, one family member felt that the DA had been presented too soon because the patient’s prognosis was still good. One of these family members suggested it be linked to worsening patient condition, he explained

Obviously the doctor or nurse is thinking ahead but I don't want to know all possible bad outcomes. But don't wait too long before communicating what has gone wrong - if we had four days – take the first two days to start thinking about worrisome trends – and alert me for decision-making in next few days.

Another family member commented

I'm glad I got this early on. I can see how this can be very helpful in making a decision about care.... We could be faced with [my husband] getting sicker and this would help then.

No issues were raised that reflected concerns about the acceptability of the DA.

Balance

Of 11 participants, 9 (82%) thought the DA was completely balanced and 2 family members (who felt that their relative would prefer comfort care) thought it was a little slanted to comfort care. No issues were raised that reflected concerns about the balance of the DA.

Understandability

Of the 11 participants who gave feedback about clarity of the DA, 8 thought most things were clear, 3 family members thought everything was clear. Four family members with high school education or less felt that most things were clear. The questions that family members asked as they completed the DA suggested that they understood the material in the DA and could use this to identify questions related to decision-making about life support. No issues arose related to comprehension of the DA.

Potential to Have Desired Impact Without Adverse Consequences

After reviewing the DA, 7 of 9 (78%) family members who responded to the survey felt moderately prepared to discuss decisions about life support (Table 6). Families indicated that the DA helped them recognize the decision, identify questions, know that the decision depends on what matters most to the patient, organize their thoughts about the decision, think about and talk to the ICU team about what matters most to them, and helped the ICU team understand the issues that were most important to the patient. All four healthcare professionals agreed that family members were moderately prepared. One healthcare professional commented:

I think I am just inferring from when we talk that we are all on the same page but we may not be, so we need to reassess that. So this [DA] is obviously very helpful...there is obviously a huge difference in knowledge level and experience with families.

Decision coaches confirmed that the families recognized that a decision had already been made and could be reviewed with their input in future. All nine family members were able to use the DA to identify and discuss patients' values associated with features of options with the decision coach and, when present, other family members. Of eight index patients, five (63%) received the option consistent with the family's perception of patient values and preference.

Family members had clinically significant levels of distress at recruitment with a median Impact of Event Scale (IES) score of 38 (range 17-62). The family member who did not complete the DA reported the highest IES score (62). Of six family members providing data about distress both before and after the DA intervention, median levels of distress were 35 (range 17-55) at baseline and 32.5 (range 8-41) after using the DA (Table 7). One family member reported increased distress after the DA: She was frustrated because, although family members felt prepared to discuss the decision, the intensivist did not engage in SDM during the family meeting (IES score 32 to 34).

Discussion

This is the first known study examining the IPDAS criteria for field testing a DA, as part of the development process. The field testing criteria provided a structured approach for determining that the novel life support DA seems to do what was intended without adverse consequences. The study showed that the DA was feasible to implement with family members in ICU to prepare for family meetings, though it stops short of being used during family meetings. It is acceptable and understandable to users, and provided balanced information. Exposure to the DA has the potential to improve knowledge about the life support decision and clarify patient and family members' personal values regarding the features of options. Importantly, it did not appear to further

augment family member's level of distress. The DA appears to satisfy all of the field test criteria except that the DA was not used during family meetings and less than 66% of families went on to discuss values with their practitioner, became involved in preferred ways, and received the option that was consistent with the family member's perception of the patient's values and preference. Field testing as part of the DA development process provides useful information to guide further study of DA effectiveness.

IPDAS Criteria for Field Testing

The IPDAS criteria provided guidance for field testing and focused on the feasibility of using the DA, acceptability of the DA, and potential to improve knowledge and clarify values associated with options. As well, there were instruments available to measure these outcomes. The easiest way to measure feasibility of use appeared to be collecting the DA from each family member combined with observation and field notes of families' and healthcare professionals' experience using the DA. We were able to demonstrate that the DA was used by 89% of family members and felt that identified barriers to use were resolvable. For example, one family member experiencing considerable distress may have been able to use the DA given more time or more support to consider the decision with the ICU team.

During the semi-structured interview we learned more about the preferred timing of the DA. Families in the study gave mixed feedback about preferred timing (e.g. preferred the DA earlier or later) and were unsure if their intensivist wanted them to consider the options. Other SDM researchers have suggested the timing of decision support in other settings has been most effective when people are actively considering the options [12]. Since the index patients were all receiving life support, explicit consideration of the decision to continue, withhold or withdraw life support was relevant to all families in our study. ICU researchers have suggested that interventions to improve the quality of communication about life support were useful early in the ICU stay to establish relationships and prevent conflicts during the decision-making process; for example within 72-96 hours of admission [39-44]. In future, it may be necessary to

ensure the decision is explicitly raised by the healthcare professionals in the clinical context to set into motion families' consideration of the life support decision.

While the DA seemed to prepare family members for SDM, the DA stops short of impacting communication during family meetings and therefore did not meet the criterion “the DA is used by at least 66% users during family meetings”. Considering that SDM is an inherently dyadic activity which requires particular patterns of communication from both patients/families and healthcare professionals, SDM may not have occurred because we did not also prepare healthcare professionals. In a systematic review of interventions to improve the adoption of SDM in routine clinical practice [45], only the three studies that combined a DA with training of the healthcare professionals involved with SDM reported that patients perceived higher involvement in SDM [46-48]. Additional barriers that were identified during field testing included that healthcare professionals lack time and have inadequate SDM skills. These were similar to the top barriers to the adoption of SDM by healthcare professionals that were identified in a systematic review of 38 studies [49]. Some researchers have found that patient mediated knowledge translation interventions, like DAs, improve agreement between patient preferences and ensuing healthcare decisions [50]. Others have suggested that they may be insufficient to change the nature of the decision-making interaction unless they also influence healthcare professional behaviour [9]. In future, the DA should be implemented with training for healthcare professionals to better prepare them for SDM with families who have been activated for SDM by completing the DA.

Evaluating acceptability was fairly straightforward and we were able to demonstrate that the DA was acceptable to 100% of participants using the Acceptability survey that has been used in many DA studies [25,26]. Although we supplemented this survey with qualitative questions to better understand some elements of acceptability, these findings did not provide additional information and we would not necessarily include qualitative data for subsequent field testing studies.

It was more challenging to measure balanced presentation of options by individuals neutral to the decision. One issue for measuring balanced presentation is asking participants their preference prior to using the DA. Establishing a preference prior to using the DA might artificially anchor the decision and preclude explicit consideration of the options necessary for informed decision-making [51]. Families recruited for our study had a relative recently admitted to the ICU and had not yet had a family meeting, therefore, we assumed that they were at the point of decision-making. In our study, preference for a specific option was measured after the values clarification exercise. Regardless, we were able to collect data on balance from users which reflected that the large majority of family members and all healthcare professionals (82%) felt the DA presented a balanced perspective. Interestingly, those who thought it was slightly biased in one direction both indicated that the bias was consistent with their preference. Previous research found that those rating DAs as biased indicated the bias in the opposite direction to their preference [52]. Therefore, the criteria related to balance could be revised to “assess whether people facing the decision felt that the information was presented in a balanced way” rather than obtaining feedback from people who were undecided and potentially artificially anchoring them prior to using the DA.

Another challenge was determining whether the DA could be understood by individuals with limited reading skills. We recognize that this is important because decision support may be particularly helpful to engage those family members with lower education and health literacy [42]. This is not only a challenge for field testing but also a concern for many studies that have limited participation from individuals of low health literacy and/or diverse cultural groups [53-55]. Nevertheless, the DA in this study was written in plain language and evaluated at a Flesch-Kincaid grade 8 reading level. We had a signal from our field test that the DA may be completed and understood by users with limited reading skills (e.g. four participants with grade 8-12 education rated the DA as mostly clear). However, we did not evaluate understanding directly. The most common approach to measuring understanding in other studies is with a knowledge test. However, the DA in our study was designed for use with patients being admitted to ICU

with any medical condition. Therefore, this standard approach to measuring understanding was inappropriate for our study; family members' understanding of their relative's particular situation needed to be verified with the healthcare professional using the questions in the DA.

In terms of achieving the desired effect, the DA seemed to prepare family members for SDM and demonstrated that these criteria could be operationalized during field testing. For example, criteria that performed well included that family members were able to recognize a decision needs to be made, knew options and their features, understood that values affect the decision, and were clear about option features that matter most. However, IPDAS effectiveness criteria that did not perform well during field testing include those requiring concomitant changes to professionals' behavior. For example, findings indicated that healthcare professionals did not use the DA during family meetings and were not as likely to discuss patient values, have family members become involved in preferred ways and show an improved match between the chosen option and the features that matter most to the informed patient. Given the inherently dyadic nature of SDM, it may be unrealistic to expect that a DA that targets patients' preparation for SDM will impact criteria that require changes in the patterns of communication with healthcare professionals unless these professionals are also prepared for SDM [45]. Therefore, criteria for field testing as part of the DA development process could more narrowly focus on potential effects that are directly impacted by the DA, such as potential to help patients/families recognize a decision needs to be made, understand their role in SDM, know options and their features, understand that values affect decision, and be clear about option features that matter most.

Family Member Distress

Despite the fact that avoiding adverse consequences is important for some field testing [21,22], the IPDAS collaboration did not include field testing criteria about monitoring for adverse consequences. We felt that this was important, given the sensitivity of the life support decision and the known distress families experience during ICU admission [3]. As expected, participating family members' median level of distress

regarding the patients' critical illness in ICU was clinically significant at baseline (e.g. moderate or severe). However, 5 family members (78%) did not appear to have higher distress after the DA. The level of distress observed in our study was consistent with other studies of family members in the ICU [56,57]. The one family member who chose not to complete the DA had the highest levels of distress and avoided discussion of the decision with the healthcare team. Other studies have shown that participants with avoidant coping styles were less likely to seek help [58] and more likely to experience continued distress [59]. Highly distressed family members may require more support to be involved in SDM with an intervention targeting their coping, and mobilized prior to or with the DA intervention. Given the potential to decrease distress, or at a minimum not worsen distress, future studies to evaluate effectiveness of the DA should measure its impact on distress and the Impact of Event Scale seems to be an appropriate choice [60]. Finally, depending on the sensitivity of the decision or extent to which adverse consequences might impact SDM, it seems reasonable to monitor adverse consequences during field testing.

Suggested Criteria for Field Testing

This approach to field testing as part of the DA development process appeared to provide useful findings to indicate that the DA is ready for study to determine its effectiveness. More specifically, the field testing provided insight about the criteria, outcomes, data collection methods, and markers of success that could be most helpful at this particular stage of development (Table 8).

Limitations

There were three main limitations. First, some of the instruments used in this study had not been used in the ICU setting [25-31]. To overcome this limitation, multi-method data collection with triangulation of results revealed remarkably congruent accounts of the individual family's experience with SDM from the perspective of family member(s), professional, third observer and researcher field notes. Another limitation was operationalization of field testing criteria that resulted in items that were not conceptually distinct. Nevertheless, we provided definitions for each of the criteria and

examined the challenges encountered during our field testing experience. A third limitation was the small scale on which the field test was conducted and the fact that participants were recruited from one ICU. Given that there was inadequate direction from the literature to suggest how many participants are needed for a field test of a DA, we aimed to test the DA with enough people and garner sufficient evidence from a variety of measures in order to determine that the DA should proceed to a full effectiveness evaluation. Furthermore, similar sample sizes in other pilot studies have allowed adequate information about feasibility of implementing and evaluating other interventions [61,62].

Conclusions

We were successfully able to operationalize the IPDAS field testing criteria in the context of our initial evaluation of a novel DA “*Understanding the options: Planning for a family member’s care during their critical illness.*” We demonstrated that the DA was feasible to use with the majority of family members of the patients in ICU in preparation for the family meeting, families and healthcare professionals rated it as acceptable, balanced and the DA appeared to be understood by users. The DA seemed to help family members know more about the life support decision and families were able to clarify patients’ values for the options. Field testing as part of the DA development process appears to provide useful findings to indicate that a DA is ready to initiate a study to determine its effectiveness. More specifically, the field testing provided insight about the criteria, outcomes, data collection methods and markers of success that were most helpful at this particular stage of development (Table 8). In general, field testing should demonstrate that DAs are 1) feasible to use with patients/ families facing the decision and healthcare professionals who provide support during decision-making, 2) acceptable to users, and 3) have the potential to do what is intended, and 4) do not seem to present adverse consequences to users.

Competing Interests

The authors declare no competing interests.

Author's Contributions

JK designed the study with support from IDG, DS, WP and DH. JK recruited, enrolled and collected data from participants with the research assistant CF. JK analyzed the data with support from IDG and DS. All authors contributed to, reviewed, and accepted the final version of the manuscript.

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Figure 1 Field testing flowchart

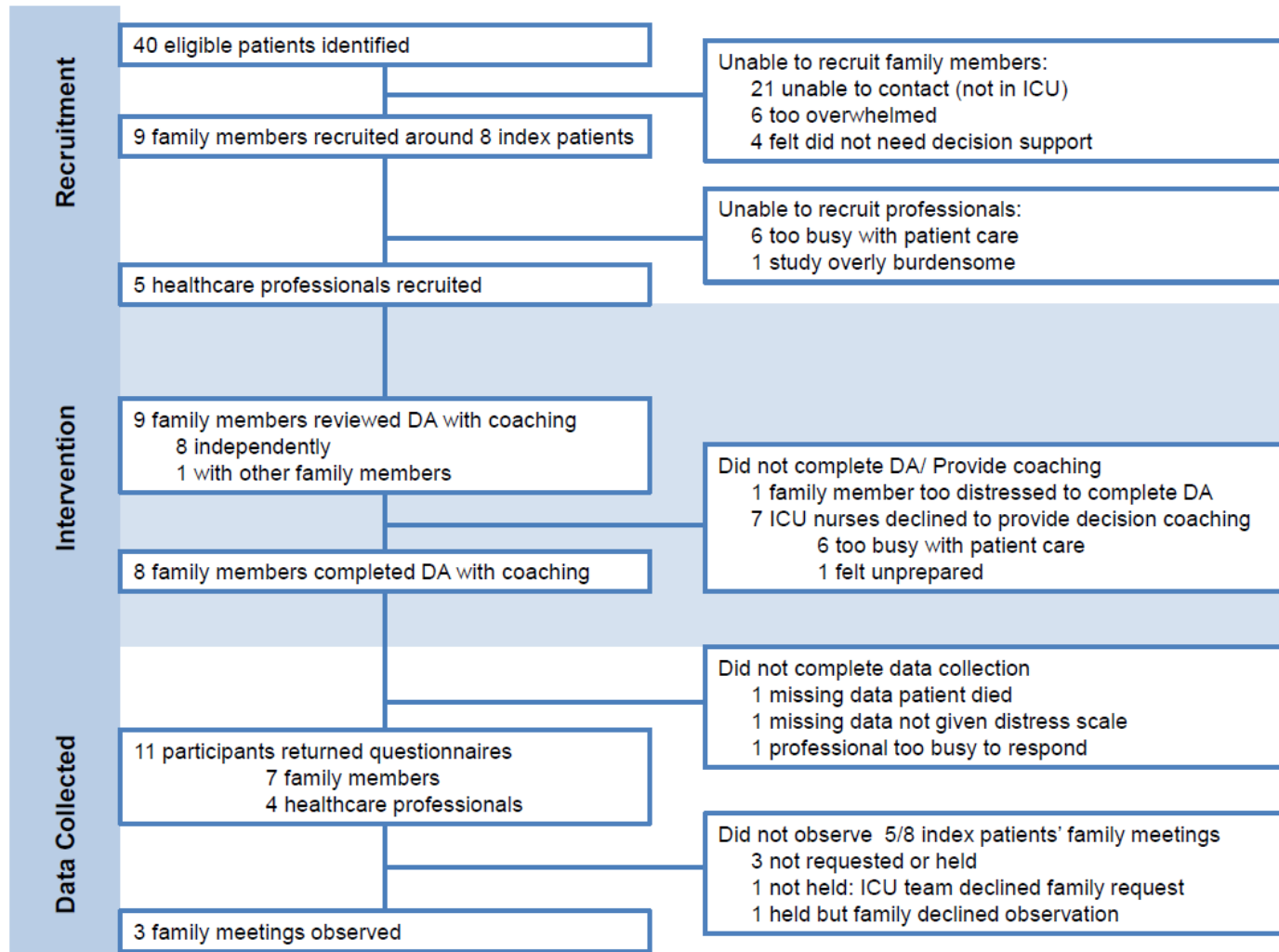


Table 1 Field testing methods

Criterion	Family	Healthcare Professionals
What is the feasibility of using the decision aid (DA) with families / healthcare professionals in the ICU setting?		
DA use by family members	Survey: Did you read the entire guide*? ¹ Did you use the summary report? ¹	Survey: Did you read the entire guide? ¹ Did you use the summary report? ¹
Barriers to use	Did anyone else help family members complete the guide? ¹ Did anyone else review the summary report? ¹ Semi-structured interview: Did you use the family guide to think about decisions regarding the care of your family member in ICU? How did you use the guide? How often? Who helped you complete the guide? Did you use it more than once? Did you use it to prepare for meetings between healthcare team and family members? Collected DA. Field notes of families' experience using the DA.	Did anyone else help family members complete the guide? ¹ Did anyone else review the summary report? ¹ Semi-structured interview: Did you use the summary report or information you learned while coaching families to think about the family's involvement in decisions regarding the patient's care in ICU? How did you use the guide / summary? How often? Did you ask questions to clarify answers given to the guide? Did you help family members complete the guide? More than once? Did you use it to prepare for meetings or conversations with family members? With whom did you share information from the guide/summary? Field notes of willingness to provide decision coaching.
DA use during family meeting	Third observer attended and/or audio recorded family meetings and rated whether: Elements of DA were discussed ² The clinician draws attention to an identified problem as one that requires a decision process. ³ The clinician states that there is more than one way to deal with the identified problem (equipoise). ³ The clinician assesses the family's preferred approach to receiving information to assist decision-making. ³ The clinician lists options which can include the choice of no action. ³ The clinician explains the pros and cons of options to the family (taking "no action" is an option). ³ The clinician explores the family's expectations or ideas about how the problem(s) are to be managed. ³ The clinician explores the family's concerns (fears) about how the problems are to be managed. ³ The clinician checks that the family's has understood the information. ³ The clinician offers the family's explicit opportunities to ask questions during the decision-making process. ³ The clinician elicits the family's preferred level of involvement in decision-making. ³	

Criterion	Family	Healthcare Professionals
	The clinician indicates the need for a decision-making (or deferring) stage. ³ The clinician indicates the need to review the decisions (or deferment) ³ Field notes of families' experience using the DA and barriers/ facilitators to using DA in deliberation.	
How acceptable is the DA to families and healthcare professionals?		
Acceptable	Survey: How would you rate the amount of information in the guide? ¹ How helpful is the guide in helping family members make decisions about treatment options? ¹ Would you recommend this guide to other family members who are considering care options for a patient with critical illness? ¹ Overall, how would you rate the guide? ¹ How would you rate the amount of information in the summary report? ¹ Overall, how would you rate the summary report? ¹ Field notes about any issues that arose related to acceptability. Semi-structured interview: Was the timing of decision support acceptable? Would you have like to receive the guide earlier? Or later in your hospital stay? What were the advantages (or disadvantages) of getting information about decision-making?	Survey: How would you rate the amount of information in the guide? ¹ How helpful is the guide in helping family members make decisions about treatment options? ¹ Would you recommend this guide to other family members who are considering care options for a patient with critical illness? ¹ Overall, how would you rate the guide? ¹ How would you rate the amount of information in the summary report? ¹ Overall, how would you rate the summary report? ¹ Field notes about any issues that arose related to acceptability. Semi-structured interview: Was the timing of decision support acceptable? Would you have like use the guide with families earlier? Or later in their hospital stay? What were the advantages (or disadvantages) of getting information about decision-making?
How balanced is the presentation of options in the DA?		
Balanced presentation	Survey: How balanced was the guide's information about type of care in ICU? ¹ Field notes to capture feedback about presentation of the options.	Survey: How balanced was the guide's information about type of care in ICU? ¹ Field notes to capture feedback about presentation of the options.
How understandable is the DA to families and healthcare professionals?		
Understood	Survey: How clear was the information in the guide? ¹ Semi-structured interview: Did you need help to complete the guide? (to get insight	Survey: How clear was the information in the guide? ¹ Semi-structured interview: Did you ask questions to clarify answers given to the guide?

Criterion	Family	Healthcare Professionals
	about understanding) Observed comprehension of the DA during use. Field notes of families' questions to researchers as they used the DA and about any issues that arose related to comprehension.	Did you help family members complete the guide?
What is the potential to have the desired impact?		
Potential to help families recognize a decision needs to be made.	Survey: Did the information and support you received help you recognize that a decision needs to be made? ⁴ A health problem was identified and it was made clear that a decision was needed. ⁵	Survey: A health problem was identified and it was made clear that a decision was needed. ⁵
Potential to help families know options and their features.	Survey: Did the information and support you received help you think about the pros and cons of each option? ⁴ Did the information and support you received help you identify questions you want to ask the ICU team? ⁴ More than one way to manage the health problem was described. ⁵ Different options (including the possibility of doing nothing) were discussed. ⁵ The advantages, disadvantages and possible outcomes of options were discussed. ⁵ Ideas or expectations about managing the health problem were discussed. ⁵ Concerns or worries about managing the health problem were discussed. ⁵ It was made sure that information had been understood. ⁵ There were opportunities to ask questions. ⁵	Survey: Did the support provided help family fully understand the risks and benefits of each option? ⁴ More than one way to manage the health problem was described. ⁵ Different options (including the possibility of doing nothing) were discussed. ⁵ The advantages, disadvantages and possible outcomes of options were discussed. ⁵ Ideas or expectations about managing the health problem were discussed. ⁵ Concerns or worries about managing the health problem were discussed. ⁵ It was made sure that information had been understood. ⁵ There were opportunities to ask questions. ⁵
Potential to help families understand that values affect decision.	Survey: Did the information and support you received help you know that the decision depends on what matters most to the patient? ⁴	

Criterion	Family	Healthcare Professionals
Potential to help families be clear about option features that matter most.	<p>Survey: Did the information and support you received help you think about which pros and cons are most important?⁴ Did the information and support you received help you organize your own thoughts about the decision?⁴ Did the information and support you received prepare you to talk to the ICU team about what matters most to you?⁴ Collected the DA to verify that family members were able to respond to the values clarification section of the DA. Field notes about the potential of the DA to clarify patient values with their family.</p>	<p>Survey: Did the support provided help family identify the importance that the patient would place on the risks and benefits of each option?⁴</p>
Potential to help families discuss values with their practitioner.	<p>Survey: Did the information and support you received prepare you to talk to the ICU team about what matters most to you?⁴ Did the information and support you received prepare you for a family meeting with the ICU team?⁴</p>	<p>Survey: Did the support provided prepare family for discussion during meetings with member of the ICU healthcare team?⁴ Did the support provided help you more fully understand the issues that are most important to the patient?⁴ Did the support provided facilitate your discussion with family members?⁴ Did the support provided improve the way your time was spent in discussion with family members?⁴ Did the support provided improve the quality of your discussions with family members?⁴ Field notes about the potential of the DA to clarify patient values with their healthcare professionals.</p>
Potential to help families become involved in preferred ways.	<p>Survey: Did the information and support you received help you think about how involved you want to be in the decision?⁴ The preference to take part in the decision (or not) was respected.⁵</p>	<p>Survey: Did the support provided help family be as involved in the decision-making process as they desired?⁴ Did the support provided help you tailor your counseling to their preference for decision participation?⁴ The preference to take part in the decision (or not) was respected.⁵</p>

Criterion	Family	Healthcare Professionals
Potential to improve match between the chosen option and the features that matter most to the informed patient	<p>Survey: Did the information and support you received prepare you to make a better decision?⁴</p> <p>Collected DA: match between family perception of values and preference and implemented option.</p>	<p>Survey: Did the support provided help the family make a more informed decision?⁴</p>
What is the potential for adverse consequences?		
Psychological distress	<p>Impact of Event Scale⁶ before and after DA intervention.</p> <p>Field notes: recorded reasons for non-participation/ reasons unable to complete the DA.</p>	Field notes: recorded reasons for non-participation/ unable to coach families.
<p>*guide refers to DA (in the original questionnaire to families referred to the decision guide or guide)</p> <p>¹ Acceptability Survey [25,26].</p> <p>² Family Meeting Observation Checklist (developed for this study based on elements of DA)</p> <p>³ Third observer OPTION instrument [27,28].</p> <p>⁴ Preparation for Decision Making Scale (agreement with statements from 'not at all' – 'a great deal')[29,30].</p> <p>⁵ Dyadic OPTION instrument (agreement with statements from 'Strongly agree' to 'strongly disagree')[31]</p> <p>⁶ Impact of Event Scale (rated 'Not at all' – 'often') [32]</p>		

Table 2 Characteristics of enrolled participants

Demographic	Family Member n=9	Healthcare Professional n=5
Relationship to patient	5 Spouse 3 Child 1 Sibling	2 Intensivist 3 Nurse
Legal surrogate decision-maker		
yes	7	0
no	1	5
missing	1	0
Age in years [median (range)]	42 (28 – 70)	38 (29 – 64)
Sex		
male	3	1
female	6	4
Marital Status		
married	8	4
divorced/single	1	1
Highest level of education		
Some high school	1	0
High school	3	0
College	2	1
University	2	4
Master's	1	0
ICU Experience in years [median (range)]	N/A	3 (2- 30)
Role preference		
Family makes the decision	1	0
Family makes the final decision considering doctor's opinion	2	1
Doctor and family share responsibility for deciding	5	4
Doctor makes the final decision considering family's opinion	1	0

Table 3 Use to prepare for family meetings

Item	Family n=9	Healthcare Professional n=4
Read Guide*		
Yes	9	4
No	0	0
Shared Summary*		
With ICU team	8	0
With other family members	3	0
Received help with guide^		
Decision coaching by research nurse	8	N/A
Decision coaching by ICU nurse	1	N/A
Used DA/summary to think about life support decision^		
Yes	9	3
No	0	1
* Acceptability Survey [25,26]		
^ Field notes, Semi structured interview question		

Table 4 Use during family meetings

DA Element	Family meeting ¹		
	✓ Discussed ² (OPTION) ³		
	A	B	C
Problem requires a decision process ³	3	1	4
Situation before ICU ²			
Health problem	✓	✓	✓
Prior functional status (PPS)	✓	-	✓
Prior quality of life (Missoula-VITAS Quality of Life Index)	✓	-	✓
Situation right now ²			
Organ system failure	✓	✓	✓
Types of life support considered reasonable for this patient	✓	-	✓
More than one way to deal with problem (equipoise) ³	- (1)	- (0)	✓ (4)
Assesses the family's preferred approach to receiving information ³	- (1)	- (0)	- (0)
Lists options which can include the choice of no action ³	✓ (3)	- (1)	✓ (4)
Present options ²			
Life support	✓	✓	✓
Comfort care	✓	-	✓
Other (e.g. cardiopulmonary resuscitation)	✓	-	-
Explains the pros and cons of options (taking "no action" is an option) ³	✓ (3)	- (1)	✓ (4)
Explores the family's expectations or ideas about management ³	✓ (2)	- (1)	✓ (4)
Discuss values ²			
Advanced directive or other document	-	-	-
Discussed use of ACP documents	-	-	-
Patient values for options	✓	-	✓
Family values for options	✓	-	✓
Healthcare team values for options	✓	✓	✓
Explores family's concerns (fears) about management ³	- (1)	- (1)	✓ (4)
Checks understanding ³	- (1)	- (1)	✓ (4)
Evaluate progress in decision-making ²			
Feeling informed	-	✓	✓
Uncertainty	✓	-	✓
Clear values	-	-	✓
Support needs	-	-	✓

Quality of decision	-	-	✓
Next steps	✓	✓	✓
Time to revisit decision	✓	-	✓
Opportunities to ask questions ³	✓(2)	✓(2)	✓(4)
Elicits the family's preferred level of involvement ³	✓(4)	- (0)	- (0)
Discuss others perspectives ²			
Identify other family members/professionals involved	✓	✓	✓
Discuss other perspectives affect decision-making	✓	-	✓
Discuss preferred role in decision-making	✓	-	-
Discuss preferred choice	-	✓	✓
Indicates need for a decision-making (or deferring) stage ³	✓(3)	- (1)	✓(4)
Indicates need to review the decisions (or deferment) ³	✓(4)	- (0)	✓(4)
Total Elements of DA discussed²	17	8	20
Total OPTION score³	28	9	40

¹ Family meetings held for 4/8 index patients; 3 meetings (A,B,C) were observed / audio recorded

² Family Meeting Observation Checklist (✓element of DA discussed; Total summed score 0-24)

³ Third observer OPTION rating (0 = No attempt; 1 = Perfunctory attempt; 2 = Baseline skill level; 3 = Some exploration; 4 = Observed and executed to a high standard; Total summed score 0-48)
[27,28]

Table 5 Acceptability

Item*	Family n=7 # responses	Healthcare professional n=4 # responses
Amount of information		
Much less than I needed	0	0
A little less than I needed	0	1
About the right amount	5	3
A little more than I needed	1	0
A lot more than I needed	1	0
Helpfulness		
Very helpful	2	0
Somewhat helpful	4	4
A little helpful	1	0
Not helpful	0	0
Timing acceptable		
Appropriate	5	4
Earlier	0	0
Later	2	0
Recommend to other family members		
Definitely	4	2
Probably	3	2
Probably not	0	0
Definitely not	0	0
Summary rating of DA		
Poor	0	0
Fair	0	0
Good	1	2
Very good	5	2
Excellent	1	0
* Acceptability Survey [25,26]		

Table 6 Potential to have desired impact

Item	Family n=7 median (range)	Healthcare Professional n=4 median (range)
<i>Potential to help families to recognize a decision needs to be made.</i>		
DA helped family recognize that a decision needs to be made ¹	4 (1-5)	N/A
Health problem identified / made need for decision clear ²	3 (3-4)	3 (3)
<i>Potential to help families to know options and their features.</i>		
DA helped family think about pros and cons of each option ¹	3 (1-5)	3 (2-4)
DA helped family identify questions about options ¹	4 (2-5)	N/A
More than one way to manage problem described ²	3 (2-3)	3 (3-4)
Different options discussed ²	2 (1-4)	3 (3)
Advantages, disadvantages, possible outcomes discussed ²	3 (2-4)	3 (3-4)
Ideas or expectations discussed ²	3 (2-4)	3 (2-4)
Concerns or worries discussed ²	3 (2-4)	3 (3)
Made sure information was understood ²	3 (2-4)	3 (2-3)
Opportunities to ask questions ²	4 (3-4)	4 (3-4)
<i>Potential to help families to understand that values affect decision.</i>		
DA helped family know decision depends on patient values ¹	4 (1-5)	N/A
<i>Potential to help families to be clear about option features that matter most.</i>		
DA helped family think about importance pros and cons ¹	4 (1-5)	3 (2-3)
DA helped family organize their thoughts ¹	4 (1-5)	N/A
DA prepared you to talk to the ICU team about values ¹	4 (1-5)	N/A
Able to respond to the values clarification in DA ³	9/9	N/A
<i>Potential to help families to discuss values with their practitioner.</i>		
DA prepared family for a meeting with the ICU team ¹	4 (1-5)	2.5 (2-4)
DA helped ICU team understand patient values ¹	4 (1-5)	3 (2-3)
DA improved the way professionals' time was spent ¹	N/A	3 (3)
DA facilitated discussion with family members ¹	N/A	3 (3-4)
DA improved quality of professionals' discussions ¹	N/A	3 (3)
<i>Potential to help families to become involved in preferred ways.</i>		
DA helped family think about how involved they want to be ¹	4 (1-5)	N/A

DA helped family be as involved as they desired ¹	N/A	4 (2-4)
DA helped tailor counseling to preference for involvement ¹	N/A	3 (2-3)
Preference for involvement respected ²	3 (3-4)	3 (3-4)

Potential to improve the match between the chosen option and the features that matter most to the informed patient.

DA prepared family to make better / more informed decision ¹	3 (1-5)	3.5 (2-4)
Match between family preference, patient values and implemented option ⁴	6/8	N/A

¹ Preparation for Decision Making Scale (Scale: 1= Not at all; 2= A little; 3= Somewhat; 4= Quite a bit; 5= A great deal; Total summed score 10-50)[29,30].

² Dyadic OPTION instrument (1= strongly disagree; 2= disagree; 3= agree; 4= strongly agree; Total summed score 12-48)[31]

³ Semi structured interview question, field notes with all 9 family members

⁴ Review of DA for 8 index patients completed by family, field notes

Table 7 Potential influence on family member psychological distress

Item	Baseline n=6* median (range)	Post DA n=6* median (range)
Intrusiveness subscale		
1. I thought about it when I didn't mean to.	3 (3-5)	3 (0-5)
4. I had trouble falling asleep or staying asleep because of thoughts about it that came into my mind.	3 (1-5)	4 (1-5)
5. I had waves of strong feelings about it.	4 (3-5)	4 (1-5)
6. I had dreams about it.	0.5 (0-3)	0 (0-3)
10. Pictures about it popped into my head.	3 (0-5)	3 (0-5)
11. Other things kept making me think about it.	3 (1-5)	2 (1-5)
14. Any reminder brought back feelings about it.	3 (1-5)	3 (1-5)
Avoidance subscale		
2. I avoided letting myself get upset when I thought about it or was reminded of it.	3 (0-5)	1 (1-5)
3. I tried to remove it from memory.	1 (0-3)	1 (0-3)
7. I stayed away from reminders of it.	0.5 (0-3)	0 (0-1)
8. I felt as if it hadn't happened or wasn't real.	1.5 (0-5)	1 (0-3)
9. I tried not to talk about it.	0.5 (0-5)	2 (0-3)
12. I tried not to think about it.	1 (0-5)	2 (0-3)
13. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	3 (1-5)	1 (0-3)
15. My feelings about it were kind of numb.	3 (0-3)	1 (0-3)
Total score	35 (17-55)	32.5 (8-41)

* Missing data for 3 family member participants post DA therefore only paired data presented.

Scale: Not at all = 0; Rarely = 1; Sometimes = 3; Often = 5

Total summed score (0-75): < 8 subclinical stress, 9-25 mild to moderate degree of stress, ≥26 clinically significant with moderate or severe impact [35]

Table 8 Suggested criteria for field testing decision aids

Suggested criteria	Outcome	Data	Determination of success
1) Feasible to use with patients/ families facing the decision and healthcare professionals who provide support during decision-making (users)	Patient/ family use of the DA	Audio recorded observation and field notes	DA is used by at least 66% patient/family to prepare for deliberation with healthcare professionals.
	Issues affecting use in the clinical setting	Field notes	Identification of resolvable barriers affecting future use of the DA
2) Acceptable to users	Suitability of content, amount of information, usefulness, balanced presentation of options, clarity	Survey: Acceptability	The content and presentation of the DA are acceptable to at least 66% users.
	Preferred timing	Qualitative interview	The DA is considered useful by at least 66% users.
3) Has the potential to do what was intended	Potential to help both patients, families and healthcare professionals recognize a decision needs to be made, understand their role in decision-making, know options and their features, understand that values affect decision, be clear about option features that matter most	Survey: Preparation for Decision-making Scale	The DA has intended effect for at least 66% users
4) Does not seem to present adverse consequences to users	Potential to cause patient/family clinically important distress during decision-making	Impact of Event Scale	Adverse consequences experienced by users are minimal or balanced by the potential benefit of the DA
	Identify potential to interfere with decision-making process including reasons for non-participation or unable to complete the DA	Field notes	

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Chapter 5: Integrated Discussion

While the dissertation was a collaborative effort, here I provide my own reflections about what I learned about the process of developing the patient decision aid (DA) to involve family in decisions about life support for their relative in the Intensive Care Unit (ICU). First, I describe how the dissertation contributes to theory in terms of advancing knowledge about the systematic process of DA development using International Patient Decision Aid Standards (IPDAS) criteria. Then, I examine how the studies contribute to theory with respect to validating the Interprofessional Shared Decision Making (IP-SDM) conceptual model beyond primary care to the ICU context. Finally, I highlight further implications for nursing considering practice, education, and future research (Table 1).

Systematic Decision Aid Development using IPDAS Criteria

Findings in the three studies in the dissertation contributed to an improved understanding of the feasibility and measurability of proposed IPDAS criteria for the systematic development of DAs (Elwyn et al., 2006) (Table 2). The systematic review was able to contribute to an improved understanding of the decision and the elements of SDM included in interventions (Chapter 2). Next, the descriptive qualitative study used the Critical Incident Technique, which proved to be an effective way to engage users to analyze the characteristics of the decision (e.g. options, protocols involved in each option, variations in patients' values for different features of options) and families' information and decisional needs (e.g. degree of difficulty making the decision, factors contributing to that difficulty, actual and preferred roles and barriers to SDM) (Chapter 3). Families were unlikely to become engaged without healthcare professionals making the decision explicit and minimizing other barriers across the decision-making process (Table 3). While families and healthcare professionals interviewed during the qualitative study lacked experience with SDM, I was able to garner sufficient information to inform the content of the DA and choices about its delivery in the ICU setting.

Table 1 Implication for Theory and Nursing

Domain	Implication for Theory
Theory	The IP-SDM model can be used to understand and facilitate family involvement in health decision-making and was validated for use in the ICU setting
	The systematic development of DA can be undertaken using the IPDAS framework validated across the three studies included in the dissertation
Implication for Nursing	
Practice	Nurses and other healthcare professionals can facilitate interprofessional collaboration in ICU during the decision-making process. Roles identified were leader (e.g. intensivist), supporter (e.g. nurse, social worker, clinical ethicist, pastoral care worker), and advocate (e.g. nurse and/or family)
	Patient values for options are important, measurable and can be communicated by families to influence decisions about life support
	Patient and family involvement in deliberation about life support interventions in ICU needs to be supported in the process of care
Education	Nurses and other healthcare professionals may need enhanced knowledge, skills, and confidence to provide decision coaching to families using the DA
	Nurses and other healthcare professionals may need enhanced knowledge, skills and confidence to promote family involvement in SDM
Research	The effectiveness of the DA should be evaluated with families in ICU settings
	The SDM process for decisions about life support should be further examined to promote family involvement

Table 2 Study Objectives and Summary of Findings

IPDAS	Objectives	Methods	Findings	Implications
Review the evidence	To explore the effectiveness of interventions to improve communication between the healthcare team, patients, their family members and surrogate decision-makers about the decision to use life support in the Intensive Care Unit (Chapter 2)	Systematic Review	<p>Identified 3162 citations: 4 were intervention trials to improve communication with patients/families about the decision to use life support in the ICU.</p> <p>All interventions included patient and family values clarification with interprofessional team member facilitating communication.¹⁻⁴</p> <p>Ethics consultations (8/9 essential elements of SDM) were more effective than usual care with regard to resource use.^{2,3}</p> <p>Structured family conferences (3/9 essential elements of SDM) resulted in decreased stress, anxiety and depression in families, met information needs, and increased focus on patient preferences.⁴</p>	<p>Patients/families had difficulty communicating their perspectives therefore patient values were not always influencing the decision.</p> <p>SDM approaches not typically used in ICU.</p> <p>Primary studies needed to more thoroughly measure the use and effectiveness of interventions inclusive of essential elements.</p> <p>Findings informed the content and structure of the DA, as well as evaluation plan during field testing.</p>
Find out what users need to discuss options	To explore family involvement in decisions about life support interventions in the Intensive Care Unit (Chapter 3)	Qualitative Study	<p>Interviewed 6 family members and 9 healthcare professionals facing the decision.</p> <p>Identified 2 options: life support, comfort care.</p> <p>Identified 8 values influencing the selection of options: maintaining quality of life, surviving critical illness, minimizing pain and suffering, not being attached to machines, giving the family enough time to adapt emotionally to the patient's health situation, judicious use of healthcare resources.</p> <p>Barriers to family involvement included: 1) Not offering alternative options, 2) Desire to avoid burdening family, 3) No specific trigger for the process, 4) Not being</p>	<p>Families and healthcare professionals lacked experience with SDM for life support decisions.</p> <p>Critical Incident Technique was an effective way to elicit information from users.</p> <p>Need to conduct further research in situations where family/healthcare professionals are involved in SDM to determine if new themes arise.</p> <p>Findings informed the content and</p>

emotionally ready to engage in the process, 5) Families not having understandable information, 6) Families not knowing what questions to ask, 7) Inconsistent messages from team, 8) Dominant influence of professionals' values, 9) Different values among family members driving preferences, 10) Difficulty reaching agreement, 11) Being unclear about patient wishes, 12) Asymmetry of power, 13) Lack of therapeutic relationship with family, and 14) Lack of interprofessional collaboration.

structure of the DA.

<p>Field test</p>	<p>To evaluate the ability to operationalize the IPDAS criteria in the context of field testing a novel DA for families facing decisions about life support for their relative in the Intensive Care Unit (Chapter 4)</p>	<p>Mixed method field test study</p>	<p>Developed DA for families intending to overcome identified barriers to SDM</p> <p>Novel DA was reviewed by experts in SDM and decision-making in ICU, general public, plain language editors.</p> <p>DA feasible to use with families and healthcare professionals in the ICU setting, acceptable to users, balanced, understood, and had the potential to improve knowledge and clarify patient and family members' values regarding the features of options, without appearing to increase family member distress.</p> <p>Observed no change to healthcare professionals' practice of SDM. Healthcare professionals feel that they lack time and lack skills in supporting SDM.</p>	<p>IPDAS criteria that did not perform well included those that required concomitant changes to healthcare professionals' behavior.</p> <p>Future DA field testing should demonstrate 1) feasibility of use, 2) acceptability to users, 3) potential to do what is intended, and 4) adverse consequences experienced.</p> <p>Healthcare professionals will need more support to use DA.</p>
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References: ¹SUPPORT, 1995; ²Schneiderman et al., 2000; ³Schneiderman et al., 2003; ⁴Lautrette et al., 2007.

Table 3 Barriers remaining after the DA intervention

Barrier	Intervention component			Experience during field testing	Suggestions for future evaluation of DA
	DA	Summary	Coach		
Barriers mostly resolved					
Family not being emotionally ready to receive information	X		X	Family members experience clinically important distress which does not seem to be increased by the intervention	Continue to monitor and report family distress Investigate hypotheses: 1) Highly avoidant families less likely to engage in SDM , 2) Family member distress diminishes throughout ICU stay, 3) Greater SDM decreases experience of distress
Desire to avoid burdening family			X		
No specific trigger for the process	X	X		DA triggered process for families to consider life support decision	
Families not knowing what questions to ask	X			Family used knowledge gaps identified by using the DA to form questions for the healthcare team	
Inconsistent messages from team		X	X	No known inconsistent messages during field test	Continue to evaluate effect of DA intervention
Different values among family members driving preferences	X		X	Values clarification exercise assisted families to verbalize and come to agreement about patient values	

Barrier	Intervention component			Experience during field testing	Suggestions for future evaluation of DA
	DA	Summary	Coach		
Barriers remaining					
Being unclear about patient wishes	X	X		Families verbalized and came to agreement about patient values. Without deliberation, healthcare team remained unaware of patient/family values	
Not including alternative options	X			ICU team minimized need to consider the decision by avoiding decision-making	
Not understanding information	X	X	X	DA helped families develop questions but there were few opportunities to ask questions	
Dominant influence of professionals' values	X	X		Family able to clarify patient values and preferences but not always discussed with healthcare team in ICU	Use DA to structure formal meeting between physician and family to discuss life support decision after family completes the DA
Difficulty reaching agreement	X	X	X	Healthcare team did not always use family conference to promote family involvement in SDM	
Asymmetry of power	X	X		Physician decided if meetings with family would occur, regardless of expressed family desire for meeting	
Lack of therapeutic relationship with family	X		X	Little deliberation with families early in the decision-making process	
Poor interprofessional collaboration		X		Healthcare professionals did not review decision summary/decision aid prior to family meetings	

Barrier	Intervention component	Experience during field testing	Suggestions for future evaluation of DA
<div style="display: flex; justify-content: space-around; font-size: small;"> DA Summary Coach </div>			
Emergent barrier identified during field test			
Professionals lack time for SDM		Nurses (6/8) perceived that helping family members complete the DA would take too much time away from care of critically ill patient	Improve engagement with DA Address attitude and beliefs about SDM Monitor time needed for decision coaching / SDM
Professionals lack skills in SDM		Nurse (1/8) felt unprepared to provide coaching	Improve preparation for healthcare professionals for SDM: develop communication and decision coaching skills to support effective deliberation

Findings from the systematic review and qualitative study as well as IPDAS criteria were used to inform the content of a novel DA to enhance family preparation to engage in SDM. The DA was titled *Understanding the options: Planning for a family member's care during their critical illness* (Appendix B). Over a period of ten months, drafts of the DA were produced in an iterative process that involved review by 1) shared decision-making experts (n=4); 2) healthcare professionals including physicians, residents, nurses, and clinical ethicists who both practiced and conducted research in the ICU setting (n=25); 3) editors with experience publishing plain language documents (n=3); and 4) adults from the general public (n=10) (Appendix D). The reviewers provided helpful advice about the clarity and simplicity of language as well as the layout, flow and overall content of the document. It was necessary for the research team to make decisions about whether to revise the decision DA as the reviewer groups had different interests and therefore the research team sometimes received conflicting advice about the DA. For example, ICU professionals wanted to include names of specific life support technologies but plain language reviewers felt that this language was inaccessible and adults from the community found it confusing. Once the substantive content of the DA stabilized, the DA was presented to healthcare professionals in the ICU where it was implemented and reviewed by the hospital Ethics Review Board. No further changes were required by these groups; therefore, at version 26 the DA was considered ready to field test with family members of patients in ICU.

Finally, IPDAS criteria were operationalized during field testing using a mixed method design which strengthened the conclusions drawn about the success of the novel DA (Table 2). IPDAS criteria that were successfully operationalized in the field test were those that demonstrated 1) feasibility of use, 2) acceptability to users, 3) potential to do what is intended, and 4) adverse consequences for users. For example, the DA was used by 89% of family members (8/9) and remaining barriers to use were resolvable (Table 3). Evaluating acceptability was fairly straightforward using the Acceptability survey that showed the DA was acceptable to 100% of participants (Barry, Fowler, Jr., Mulley, Jr., Henderson, Jr., & Wennberg, 1995; Sepucha, Ozanne, Partridge, & Moy, 2009). In terms

of achieving the desired effect, the DA seemed to prepare family members for SDM and demonstrated that these criteria could be operationalized during field testing using the Preparation for Decision Making scale (Graham & O'Connor, 1995; Bennett et al., 2009). For example, criteria that performed well included that family members were able to recognize that a decision needs to be made, knew options and their features, understood that values affect the decision, and were clear about option features that matter most (Graham & O'Connor, 1995; Bennett et al., 2009). The DA did not seem to increase family member distress measured using the Impact of Event Scale (Horowitz, Wilner, & Alvarez, 1979). IPDAS effectiveness criteria that were not successfully operationalized during field testing include those requiring concomitant changes to professionals' behavior. During the study, some health professionals inadequately involved patients and families in the process of SDM leading to decisions about life support and may require proactive or explicit support that is built into the care map/process (Table 1).

Interestingly, DAs developed using IPDAS criteria (for a complete list, see Table 1.1, p. 12) (Elwyn et al., 2006) address only the first four of the essential SDM elements (define and/or explain the problem that needs to be addressed; present the options that exist, share perspectives on the relative benefits, risks and costs of the options raised; elicit patient values and preferences including ideas, concerns, and outcome expectations) and are missing the five other elements addressed only during deliberation (discuss patient ability/self-efficacy to follow through with a plan; explain doctor knowledge and recommendations given the situation at hand; check and clarify understanding; make or explicitly defer the decision; arrange follow-up) (Makoul & Clayman, 2006). Therefore, using IPDAS criteria will inevitably create incomplete SDM interventions. Researchers should know that the balance of the SDM intervention may need to be accounted for in the delivery of the DA, if it is to potentially impact IPDAS effectiveness criteria requiring communication amongst stakeholders (e.g. discussing values with their practitioner or becoming involved in preferred ways) (Elwyn et al., 2006). When engagement of multiple stakeholders is necessary, as in SDM, it may be difficult to show an effect on the decision that is implemented until the components (DA and delivery) are put together in

the clinical settings. This was indeed the case during field testing where there was a signal that simply preparing families with the DA would not produce SDM. For example, family meetings were held for half of the patient families during field testing (4/8), the DA was not used in any of the meetings, and patient and family values were elicited in only one of the four meetings. Therefore, in the absence of an overture from healthcare professionals during the field test, the deliberation needed in the SDM process either did not happen or family members did not feel empowered to engage in discussion (Chapter 4). Families relayed that they felt prepared for SDM but experienced feelings of disappointment and distress when deliberation with healthcare professionals did not occur. Results of the field test suggested that healthcare professionals may need more support to effectively involve families using the DA intervention. Since barriers to SDM may preclude implementation of a DA in the processes of care even for long enough to establish effectiveness, further evaluation of efficacy or effectiveness remains challenging without a more complete SDM intervention.

The need for more complete SDM interventions has important implications for developing, field testing, and evaluating DAs. An important consideration is whether researchers can more effectively bring about SDM 1) by developing the DA, studying whether the DA effectively prepares patients/families, determining its effectiveness, and then examining whether it can be implemented in the processes of care; or 2) by developing a DA to structure deliberation between patients/families and healthcare professionals. Certainly, many DA developers have used the stepwise approach described in the first option (O'Connor et al., 2009). A stepwise approach to building SDM component interventions for each of the stakeholders (patients, families, professionals) would seem to ensure that researchers don't develop too many parts of an intervention with little understanding of which part might have particular effect. In terms of time, the researcher may, in a stepwise fashion, spend more time in development thereby gaining useful components towards a more complete SDM intervention. The second option, examining at once if the DA can structure deliberation between patients/families and healthcare professionals, has received increased attention. SDM researchers have

suggested that an increased focus on deliberation is needed (Elwyn & Miron-Shatz, 2009; Elwyn, Frosch, Volandes, Edwards, & Montori, 2010) if the potential gains of using DAs to prepare for involvement are to be realized (O'Connor et al., 2009). Developers have also observed that using DAs to prepare only the patient or family might not be effective, explaining that

This approach would place the onus of creating a conversation almost entirely on patients. Confronted with the expertise and authority of the clinicians, most patients may not feel comfortable enough to bring up concerns or questions that the decision aid may have provoked. From this insight, we decided that the decision aid needed to be present in the exam room during the consultation in order to have a chance at creating a conversation. (Montori, Breslin, Maleska, & Weymiller, 2007, p. e233)

Notwithstanding the approach used to develop more complete SDM interventions, it seems that delivery of the DA in the processes of care should be considered during the systematic process of developing and field testing DAs so that they might produce the deliberation essential to SDM.

Validating the IP-SDM Model in the ICU Setting

I identified the Interprofessional Shared Decision Making (IP-SDM) conceptual model (Legare, Stacey, Gagnon et al., 2010) as potentially relevant for supporting an interprofessional approach to SDM in the ICU setting. The IP-SDM model provided a helpful structure for analysis of barriers in the qualitative study (Chapter 3) and to assist with the design of the DA and its delivery to prepare family members for communication with healthcare professionals during the decision-making process about life support for the critically ill patient in ICU.

Roles of Stakeholders

Though many SDM theories identify roles for a patient – physician dyad (Braddock et al., 2008; Charles, Gafni, & Whelan, 1997; Emanuel & Emanuel, 1992; Makoul & Clayman, 2006; Towle & Godolphin, 1999), fewer consider roles for family

members (Gabe, Olumide, & Bury, 2004) or other member of the interprofessional healthcare team such as nurses (Legare, Stacey, Gagnon et al., 2010; Stacey et al., 2008). The most helpful feature of the IP-SDM model was that it focused on the patient as central to the process and made explicit that although patients' perspectives should be central to the decision, other family members and healthcare professionals also influenced the decision (Legare, Stacey, Gagnon et al., 2010). The studies conducted during the dissertation support the interprofessional approach proposed by the IP-SDM conceptual model. For example, IP-SDM suggested that a healthcare professional should initiate the decision-making process (Legare, Stacey, Gagnon et al., 2010). They should also provide non-directive support to the patient and family during the process of decision-making (decision coaching). The systematic review found emerging evidence that having someone on the interprofessional team assigned to the role of facilitating the decision-making process, similar to the decision coach role, addressed some of the essential elements of SDM and improved health outcomes (Chapter 2). The qualitative study further described three roles to facilitate interprofessional collaboration in ICU during the decision-making process: leader (e.g. intensivist), supporter (e.g. nurse, social worker, clinical ethicist, pastoral care worker), and advocate (e.g. family) (Chapter 3) (Table 2). However, family preparation alone was not sufficient to ensure SDM and remaining barriers seemed to suggest that preparation of healthcare professionals would be necessary (Chapter 4). Indeed, consistent with the structure of roles suggested by the IP-SDM model and the results of a systematic review of interventions to improve the adoption of SDM (Legare et al., in press), the results of field testing support the notion that all stakeholders (patients, families, and healthcare professionals) may need to be prepared to effectively engage in the SDM process.

Decision

Agreeing on the decision point and options available to families was important to the families' ability to engage in SDM. In the qualitative study, two barriers were identified: there was no specific trigger for the process and healthcare professionals did not identify alternative options (Chapter 3). The DA included a description of two

options, presenting the possible treatments that supported life versus a focus on comfort care. During field testing, the DA triggered the SDM process for some families. However for other families, the healthcare professionals either minimized need to consider the decision or avoided decision-making thereby flagging remaining barriers. I believe that these barriers will need to be overcome in order for families to be involved in SDM, lending further support for including this element of the IP-SDM model.

Information Exchange

In order for families to make higher quality decisions that were informed and based on the patient's values, stakeholders needed to understand enough about the options available to them in order to identify values associated with the options. Effective information exchange is a goal of SDM interventions like DAs (O'Connor et al., 2009). In the qualitative study, all healthcare professionals perceived that facilitating information exchange between families and the team was an important part of their role (Chapter 3). In terms of barriers to involvement in SDM, family member participants indicated that they received oral rather than written information and were not always able to understand that information. Further, some family members did not know what questions to ask their health care team. The DA field tested in Chapter 4 used plain language to introduce two options, life support and comfort care, and guided family members to describe their relative's health situation before coming to ICU and current situation (Appendix B). Field testing showed that family members were able to identify their knowledge gaps using the DA in order to form questions for the healthcare team (Chapter 4). Unfortunately, given that there were few opportunities to ask their questions, information needs remained unmet for many families (Table 2). Taken together, this would seem to validate that effective information exchange is essential for an interprofessional approach to SDM about life support in the ICU.

Values and Preferences

Values clarification is another essential concept of IP-SDM (Legare, Stacey, Gagnon et al., 2010). In contrast to the broader conception of life values (Rokeach, 1968), values associated with options are the individual's judgment of the desirability /

undesirability of specific elements of the option (O'Connor, Llewellyn-Thomas, Dolan, Kupperman, & Wills, 2005). Among the four studies included in the systematic review, all of the interventions designed to improve communication included enhanced discussion of values and preferences (Chapter 2). The SUPPORT study nurse interviewed patients, families or physicians separately to elicit values and preferences for resuscitation (The Writing Group for the SUPPORT Investigators, 1995). During the ethics consultation intervention in two studies, the ethics consultant explored and clarified patient values and preferences with the family and the healthcare team (Schneiderman, Gilmer, & Teetzel, 2000; Schneiderman et al., 2003). In the Famirea study, the physician invited family members to share stories that helped them understand who the patient was as a person (Lautrette et al., 2007).

The qualitative study confirmed patient values played an important role and that families could share patient's values when they were unable to speak for themselves such as when they were critically ill in the ICU (Chapter 3) (Table 2). Six values influencing the selection of the options of life support or comfort care were: maintaining quality of life, surviving critical illness, minimizing pain and suffering, not being attached to machines, giving the family enough time to adapt emotionally to the patient's health situation, judicious use of healthcare resources. Therefore the qualitative study added to what was already known about values that influence decisions about life support (Winter & Parks, 2008). As well, the qualitative study identified that some healthcare professionals expressed a concern that involving families in decision-making may be problematic because families may not know patients' values for options or consequent preferences (Chapter 3) (Table 3). Other healthcare professional participants maintained that they solicited families' perspectives on patient values for the options. Researchers who conducted a systematic review showed that family members predicted patient treatment preferences with 68% accuracy (95% CI, 63-72) across hypothetical health scenarios (Shalowitz, Garrett-Mayer, & Wendler, 2006). Interestingly, 12 studies in the review also assessed the type of error family members make: 8 studies found mixed results or no consistent trend, 3 found that they err by providing treatments that the

patient does not want, and 1 that they withheld wanted treatments (Shalowitz et al., 2006). Despite the potential for errors, family members were more accurate than healthcare professionals in the four studies where this was examined (Shalowitz et al., 2006). As a result, the novel DA was structured to include an opportunity for family members to clarify patient values and preferences for the options, as well as their own and those of other stakeholders, so that their influence on the decision about life support could be made explicit in communication with other stakeholders.

One of the challenges exemplified by the field testing study was that multiple family members could use the DA to verbalize and come to agreement about patient values but that did not necessarily lead to communication of values to all stakeholders (Chapter 4) (Table 3). Most of the structured values ratings ranged from 0 to 5 in terms of importance. Only one value, to “Be comfortable and suffer as little as possible”, was rated consistently of high importance by all family members in the field test (4 or 5 /5) regardless of preference for life support or comfort care. In addition to the structured set of values presented in the DA, two additional values for the options were added to available space in the DA by family members: 1) *Has suffered for last 12 years* and 2) *If nothing could be done to extend his life*. One family member who refused to complete the DA held values different from those of the patient and did not want to share the ICU patient’s (spouse’s) values with the healthcare team. As well, in some cases the healthcare team made recommendations about life support while they remained unaware of patient values. These findings confirmed that other stakeholders’ values can influence the decision-making process. One way to overcome this barrier in future is to consider using the DA to structure formal meetings between physicians and families to discuss the life support decision after family members complete the DA. Notwithstanding, the dissertation research supported the concept of family involvement to help clarify patient values as part of the IP-SDM process.

Preferred Choice

As part of the IP-SDM process, each of the stakeholders should identify a preferred choice and have an opportunity to discuss their preference with the group

before making a final decision (Legare, Stacey, Gagnon et al., 2010). Among the four studies included in the systematic review, all of the interventions designed to improve communication asked patients and/or families to share their preferred choice (Chapter 2). The SUPPORT study nurse interviewed patients, families or physicians separately to elicit preferred option for resuscitation but the intervention did not help patients/families communicate with their healthcare team about the decision (The Writing Group for the SUPPORT Investigators, 1995). During the ethics consultation intervention in two studies, the ethics consultant explored preferred options and facilitated communication between the family and the healthcare team (Schneiderman et al., 2000; Schneiderman et al., 2003). In the Famirea study, the physician made a recommendation and sought families' agreement with that course of action (Lautrette et al., 2007). The qualitative study identified that power asymmetry interfered with family involvement in SDM in general (Chapter 3) and could impact SDM at this stage as well. During field testing, all family members were able to identify the patient's and their own preferred choice. However, while almost all family members (8/9) were willing to discuss preferences with the healthcare team in ICU, this did not always occur (Chapter 4). Indeed, families seemed to need an invitation to share their perspectives. Therefore, having a more formalized approach such as a meeting between the healthcare team and family to discuss the life support decision once the family has completed the DA seems to be important to an interprofessional approach to SDM (Table 1).

Actual Choice

The IP-SDM model describes an extended and unfolding process of arriving at a mutual understanding through deliberation (Legare, Stacey, Gagnon et al., 2010). Ideally, this would involve communication at each stage between multiple stakeholders and lead to agreement about an actual choice, or would lead to deferring the decision if there was disagreement. Studies included in the systematic review varied in the extent to which *agreement about the actual choice* was a goal of their interventions (Chapter 2). The SUPPORT study intervention did not facilitate communication between stakeholders or identification of choice and therefore, did not address this concept (The Writing Group

for the SUPPORT Investigators, 1995). During the ethics consultation intervention in two studies, the ethics consultant facilitated deliberation between the family and the healthcare team with a goal of reaching agreement about the decision (Schneiderman et al., 2000; Schneiderman et al., 2003). In the Famirea study, the physician made a recommendation and sought families agreement, however, if family disagreed then the decision was deferred (Lautrette et al., 2007). In the qualitative study, family members and healthcare professionals agreed that the actual choice needed to be made after they communicated with families and that this was generally a leadership role assumed by the senior physicians in ICU. Indeed, during field testing the ICU physician also assumed responsibility for making the actual choice about whether or not to use life support (Chapter 4). However, without communication at prior stages about patient values and preferences, as the IP-SDM model suggests, the actual choice was not reflective of a high quality decision.

Environment

The IP-SDM model assumes that an interprofessional approach to SDM with families in ICU would be influenced by factors at the ‘meso’ level (e.g. healthcare teams and organizations) and at the ‘macro’ level (e.g. health policies, social context and professional organization). Interventions trialled in the studies included in the systematic review focused on communication with patients and families by including a structured role for one healthcare professional but did not address meso or macro level factors (Chapter 2). Barriers to family involvement in SDM were identified in the qualitative study (Chapter 3) and during field testing (Chapter 4) and included lack of interprofessional collaboration, asymmetry of power, lack of time and lack of skills in SDM (Table 3). DAs such as the one for families considering life support may foster collaboration once implemented in the process of care; however, this is beyond the scope of DA development and field testing undertaken here. Since organizational culture varies considerably between ICUs (Baggs et al., 2007), researchers should expect that barriers to SDM might differ between ICU settings and additional strategies may be needed to overcome such barriers. Further research in other ICU settings and in situations where

family and diverse healthcare professionals are better involved will contribute to describing the optimal environment for an IP-SDM approach to the delivery of the DA in the process of care.

In summary, these studies validated the IP-SDM model as relevant to the decision about life support for critically ill patients in the ICU setting. Strengths of the IP-SDM model include attention to the need for deliberation amongst multiple stakeholders and identification of elements in the environment that could impact SDM. However, field testing showed that the novel DA stopped short of producing the shared deliberation essential to SDM. As well, although many of the elements of the IP-SDM model seemed to fit for the decision about life support in the ICU setting, some elements (feasibility, implementation and outcomes) were not described by results of studies undertaken during the dissertation. Since the studies undertaken here were more focused on family, the elements may not have been described because they are probably beyond family control. Therefore, I believe it would be premature to conclude that the elements not described are not relevant; rather it would be fairer to conclude that there is a need to conduct further research focused on the optimal interprofessional environment to support SDM in order to determine if those elements of the IP-SDM conceptual model are pertinent. It may also be helpful to conduct this research in ICU settings where family/healthcare professionals are involved in SDM. DA delivery informed by the IP-SDM model may further assist structuring shared deliberation in order to engage patients, families and interprofessional healthcare teams towards higher quality decisions about life support.

Implications for Nursing

This set of studies contributed many insights particularly important to nursing science. The following highlights the implications for nursing considering practice, education and future research (Table 1).

Practice

Nurses have a key role in facilitating communication between interprofessional teams in ICU and patients and their families (Ahrens, Yancey, & Kollef, 2003; Boards of

Directors of the Canadian Healthcare Association, the Canadian Medical Association, the Canadian Nurses Association, & the Catholic Health Association of Canada, 2005, Canadian Association of Critical Care Nurses, 2001; Canadian Nurses Association, 2000; Chesla, 1996). The decision support and advocate roles that explicitly acknowledged and encouraged the communication of patient and family member values associated with options in ICU definitely fits with standards of practice and competencies required of nurses. For example, professional standards for nurses in Ontario state as a guiding principle that “clients are the central focus of the professional services that nurses provide and as partners in the decision-making process clients ultimately make their own decisions” (College of Nurses of Ontario, 2009). Nurses are responsible for their professional knowledge which includes “planning approaches to providing care/service with the client and creating plans of care that address client needs, preferences, wishes and hopes” as well as advocating for systems of care where these sorts of therapeutic relationships can occur (College of Nurses of Ontario, 2009). Ethical standards for nursing practice require that nurses support informed decision-making and respect client choice by exploring the rationale for decisions (College of Nurses of Ontario, 2009). In addition to taking into account clients’ beliefs, values, wishes, the ethical standards also recommend that nurses examine their own beliefs, values and knowledge as well as those of others on the health care team (College of Nurses of Ontario, 2009). Although not specific to the decision about life support in ICU, the clinical practice guideline titled “Decision Support for Adults Living with Chronic Kidney Disease” offers many practical suggestions to improve the nurse’s ability to support patients in health decision-making (e.g. identifying decision points that patients face, screening for decision conflict, using DAs or other tools to provide decision support) (Registered Nurses Association of Ontario, 2009).

The nurses in these studies suggested that attitudes, beliefs, and knowledge impacted on their ability to engage in SDM practice. During the field testing, critical care nurse researchers provided decision coaching to all but one family (Chapter 4). Exceptionally, the one critical care nurse in ICU who agreed to provide decision coaching

was a recent graduate from a University where decision coaching is integrated in the curriculum (Stacey et al., 2009). As a result, two emergent barriers were identified during the field test that will need to be overcome: nurses in the ICU setting were concerned that lack of time and lack of skills in SDM prevented them from assuming a decision coaching type role with families (Table 2). Nurses, together with other healthcare professionals, need to provide proactive family support (i.e. explicitly built into the care map or process) which may include preparing the family with a DA and then facilitating communication at each stage to achieve SDM about life support (Table 1). In order for healthcare professionals to provide decision support for patients and families in the processes of care, they will need pre-licensure preparation and ongoing support for their professional practice.

Education

Nurses' attitudes, beliefs, knowledge, skills, and confidence in coaching families in ICU during the decision-making process may need to be enhanced to promote family involvement (Chapter 4) (Table 3). Considering that the issue transcends the decision-making process about life support in ICU and requires nurses to provide decision coaching across clinical settings, the barriers need to be addressed both in undergraduate nursing curricula and then reinforced after licensure or registration as a nurse. While practice guidelines are available to guide the nurse towards meeting professional standards (College of Nurses of Ontario, 2009; Canadian Nurses Association et al., 1999; Davidson et al., 2007; Registered Nurses' Association of Ontario, 2005; Registered Nurses Association of Ontario, 2009; Canadian Nurses Association et al., 1999), more support may be needed. For example, the clinical practice guideline titled "Decision Support for Adults Living with Chronic Kidney Disease" describes ways to improve the nurse's ability to support patients in health decision-making (e.g. participating in courses, seminars with role playing, clinical mentorship, and practicing with simulated patients) (Registered Nurses Association of Ontario, 2009). There is evidence that DA interventions paired with focused skills training has improved nurses' decision support skills for other decisions (Murray, Stacey, Wilson, & O'Connor, 2010; Stacey, Chambers,

Jacobsen, & Dunn, 2008). A systematic review of strategies to improve the adoption of SDM in clinical practice recently showed that increasing SDM occurred when patients prepared with a DA met with healthcare professionals who had received SDM training for their consultation about the decision (Legare et al., in press). Therefore, it seems likely that these barriers are not insurmountable and that nurses and other healthcare professionals can be better prepared to collaborate to initiate and support families in SDM about life support in ICU (Table 1).

Future Research

Given the positive results of field testing the DA, the next step will be to evaluate the effectiveness of the DA. A cluster randomized controlled trial, considered to be the most rigorous design to evaluate this sort of intervention (Grimshaw, Campbell, Eccles, & Steen, 2000), should be conducted with users (including patients, families and healthcare professionals) in the ICU setting and include a control group that receives usual decision support care. Findings from this set of studies can inform DA delivery and the selection of appropriate instruments to measure its effectiveness.

However, for a larger scale study to evaluate the effect of the DA on SDM, some key barriers need to be addressed: 1) not including alternative options, 2) being unclear about patient wishes, 3) lack of interprofessional collaboration, and 4) professionals lacking skills in SDM (Table 3). While some researchers have found that patient mediated knowledge translation interventions like the DA can improve agreement between patient preferences and ensuing healthcare decisions (Coulter & Ellins, 2007), others have also suggested that they may be insufficient to change the nature of the decision-making interaction unless they also influence healthcare professional behaviour (Legare et al., in press). Research in implementing SDM suggests that healthcare professionals should receive training to develop their skills in providing decision support and then be provided with feedback about their practice (Legare, Ratte, Stacey et al., 2010). For example, a multifaceted delivery strategy could include preparation of family members with the DA, skills training to better prepare healthcare professionals in ICU for their role in SDM (e.g. decision coaching, IP-SDM training), targeted timing for use of

the DA intervention (e.g. within 36 hrs of admission, and using the DA to structure family meetings (Table 3). As well, the multifaceted delivery strategy might be developed in an earlier study to prepare an effective intervention to support the nurse's decision coaching role in support of the SDM process. Further, a facilitation strategy employing an individual or group within each of the cluster sites may be needed to support and enable healthcare professionals to overcome local barriers to use as they arise (Dogherty, Harrison, & Graham, 2010; Stetler et al., 2006). An internal facilitator provided the leadership support that was central to successfully using and sustaining the use of other interventions such as clinical practice guidelines (Gifford, 2006). In summary, it will be necessary to pair the DA intervention targeting patients and families with a multifaceted strategy targeting professionals and clinical leaders within organizations to ensure that there is an "environment" where IP-SDM can occur. Further evaluation of effectiveness probably needs to occur in an environment where the 'prepared family' can collaborate with an adequately 'prepared interprofessional team' in order to produce meaningful involvement in SDM about life support for a patient in ICU.

The study of effectiveness should measure the impact of using the DA in the ICU setting on the SDM process and important patient, family, health professionals and healthcare system outcomes. The interprofessional team in ICU can be solicited to identify clinically important patient, family, and health system outcomes such as health outcomes related to critical illness, mortality, health related quality of life, length of stay and healthcare resource use. The IPDAS and IP-SDM frameworks used to guide development and evaluation of the DA to this stage may also be helpful to explicitly guide further evaluation. IPDAS identified effectiveness criteria for DA interventions which focus on decision quality: whether the decision is informed and based on patient values (Elwyn et al., 2006). The DA incorporates specific validated questions that could be used to measure the family's progress in decision-making about life support, such as recognition of serious health problems that the patient is experiencing in ICU (Le Gall JR, Brun Buisson C, & Trunet P, 1982), family expectations, presence of an advance directive, weight of values influencing selected options (Winter & Parks, 2008), choice,

preferred role in decision-making (Degner & Sloan, 1992), and modifiable factors contributing to uncertainty in decision-making (Legare, Ratte, Stacey & et.al., 2010). Paired with an assessment of family member's knowledge about the decision and the option selected for an individual patient, the questions in the DA could be used to assess decision quality. However, given the interest in whether tools like the DA actually impact communication with families, evaluation could also include outcomes like family perception of preparation for decision-making (Bennett et al., 2009) and perceived involvement in the decision-making process (Edwards et al., 2003; Elwyn et al., 2005; Melbourne, Sinclair, Durand, Legare, & Elwyn, 2010; Melbourne et al., 2010). Decision process specific instruments such as the Preparation for Decision Making Scale, OPTION, and dyadic OPTION were used for the first time in the ICU setting during field testing where it was possible to collect decision process data from both family members and healthcare professionals. Observation of family involvement was more challenging since formal meetings did not always occur and did not capture the potential involvement of families in more informal interactions. During the field test, family meeting observation was triangulated with self report data to more fully capture involvement, and families and healthcare professionals had remarkably similar perceptions of their interactions. Therefore, participant self report data may constitute an acceptable proxy for observed interactions and this should be examined in future studies. Limiting data collection to self report data may have the additional advantage of being easier to capture at several time points in the process of decision-making, which may be of interest in future studies.

Finally, if self report data from multiple stakeholders is collected in future studies, standard methodology, with its focus on individuals, has a limited ability to evaluate relationships. SDM, by definition, is a distinctly relational process and the study that reports only one stakeholder's scores makes a fundamental attribution error (Ross, 1977). For SDM to occur, at least two stakeholders are present in the interaction (e.g. the patient and/or family member(s) with a member of the healthcare team). Therefore, researchers could use measures that evaluate the SDM process from at least two perspectives and

analyze their interactions; such techniques are referred to as dyadic data analysis (Kenny, Kashy, & Cook, 2006). Instruments that have demonstrated validity and reliability at the dyad level as well as at the individual level (Legare, Moher, Elwyn, LeBlanc, & Gravel, 2007) include the decisional conflict scale (Leblanc, Kenny, O'Connor, & Legare, 2009), the mutual understanding scale (Harmsen, Bernsen, Meeuwesen, Pinto, & Bruijnzeels, 2005), and the patient-physician discordance scale (Sewitch, Abrahamowicz, Dobkin, & Tamblyn, 2003). Researchers testing other DA interventions have successfully collected such dyadic data for their SDM evaluation studies (Legare et al., 2009).

Conclusion

Between 2007 and 2010, a series of 3 studies were conducted to better inform the systematic development of a novel DA to enhance family preparation to engage in SDM about life support for their relative in the ICU. For healthcare professionals and administrators, the key findings include that the DA was feasible to use with families in the ICU setting and reported by both family members and healthcare professionals to be acceptable, balanced, and understood. The DA helped family members to know more about the options available to the critically ill patient admitted to the ICU and families were able to clarify patients' values for the options without experiencing increased distress. The limited involvement of families was reinforced and served to highlight challenges to engaging them in the process of decision-making about life support.

For SDM researchers, the studies contributed to what is known about the systematic process for developing DAs. The IPDAS criteria were operationalized to guide development efforts. A limitation of the IPDAS criteria is that they stop short of suggesting what might happen when one integrates the DA into clinical practice. The studies also validated the IP-SDM model beyond primary care showing that it is useful to conceptualize the decision-making process about life support in the ICU setting. Findings from the three studies showed the importance of eliciting patient's values for the outcomes of options and demonstrated that these can be measured and communicated to inform decision-making. An enhanced delivery strategy will be needed for future evaluation of the DA's effect on facilitating patient/family involvement.

This dissertation research is a call to action for nurses and other healthcare professionals to identify and assume an explicit role towards collaboration during the IP-SDM process. While this research contributes to a better understanding of healthcare professionals' communication with families during the decision-making process about life support for critically ill patients in ICU, there is much work to be done. As advocates in the clinical setting, nurses are well positioned to both directly and indirectly affect change that can place patients and families squarely at the center of healthcare decision-making. Patients and families need their values and preferences to be heard by healthcare professionals and need to be engaged in deliberation so that they can receive high quality care— regardless of their choice with respect to life support interventions.

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Chapter 6: Contribution of Collaborators

The purpose of this chapter is to introduce members of the research team and identify their contribution to manuscripts included in the thesis (see Table 1). Decisions about authorship were based on International Committee of Medical Journal Editors Uniform Requirements available at http://www.icmje.org/ethical_1author.html which require that authors 1) make substantial contributions to conception and design of the research, acquisition of data, or analysis and interpretation of data; 2) draft or critically revise the manuscript for important intellectual content; and 3) approve the final version.

The primary researcher, JK, is responsible for the integrity of the work as a whole and accepts responsibility for each of the manuscripts and the whole dissertation (Table 1). JK is a Registered Nurse with certification in Critical Care Nursing (Canada) and was a critical care nurse in the ICU at the Ottawa Hospital until December 2007. She was supported financially for the research by the George Bennett Dissertation Fellowship from the Foundation for Informed Medical Decision Making, and held a two year doctoral fellowship from the FUTURE Program for Cardiovascular Nurse Scientists, a one year research fellowship from the Canadian Researchers at End-of-life Network (CARENET) funded by Canadian Institutes for Health Research and Heart and Stroke Canada, scholarships from the Ontario Training Centre in Health Services and Policy Research, the Karen Taylor Nursing Bursary Fund, and an Excellence Scholarship from the University of Ottawa. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscripts or dissertation.

JK was supported by thesis committee members who collaborated in the development of the research proposal and approved the research plan, provided consultation for the research studies, participated in the analysis and contributed to the intellectual content of the manuscripts before finally approving them (Table 1). Thesis supervisors were Ian D. Graham (IDG) and Dawn Stacey (DS). IDG is a medical sociologist and Associate Professor at the University of Ottawa School of Nursing,

Affiliate Scientist at the Ottawa Hospital Research Institute, and Vice president of Knowledge Translation at the Canadian Institutes for Health Research. DS is a registered nurse and Associate Professor at the University of Ottawa School of Nursing, Director of the Patient Decision Aids Research Group, and Scientist at the Ottawa Hospital Research Institute. Thesis committee members were Wendy Peterson (WP) and Daren K. Heyland (DKH). WP is a registered nurse and Assistant Professor at the University of Ottawa, School of Nursing. DKH is an intensive care physician at the Kingston General Hospital, the Director of the Clinical Evaluation Research Unit, director of the Canadian Researchers at the End-of-life Network (CARENET), and Scientist at Queen's University.

Other member of the research team who were not members of the thesis committee made important contributions to the research studies (Table 1). Elina Hill (EH) collaborated on the systematic review during screening and data abstraction and in the writing and approval of the systematic review manuscript (Chapter 2). EH is a Masters in Arts student at the University of Victoria. Mary Ann Murray (MAM) collaborated on the systematic review during screening, data abstraction and data analysis, and in the writing and approval of the systematic review manuscript (Chapter 2). MAM also provided helpful direction in the early phases of data analysis for the qualitative study and her contribution to the success of the research is gratefully acknowledged. MAM is an Advance Practice Nurse and Clinical Manager for the Home Dialysis program at the Ottawa Hospital and was a post doctoral fellow at the University of Ottawa, School of Nursing. Carolin Fiege (CF) assisted with recruitment, data collection, and provided decision coaching during the field test. CF is a registered nurse and MScN student at the University of Ottawa and her contribution to the success of the research is gratefully acknowledged.

Table 1 Contribution of Collaborators

Element	Chapters 1,5,6	Manuscripts: Chapters 2,3,4		
		Interventions for Shared Decision-Making about Life support in the Intensive Care Unit: A Systematic Review	Family involvement in the process of decision-making about life support in the Intensive Care Unit: A qualitative study	Field testing an intervention to engage families and interprofessional healthcare teams in decision-making about life support in the Intensive Care Unit
Conceptualize & design	JK	JK DAF DS IDG	JK DS IDG WP DKH	JK DS IDG WP DKH
Collect data	JK	JK EH MAM	JK	JK CF
Analyze & interpret data	JK	JK MAM DS	JK MAM DS	JK IDG DS
Draft manuscript	JK	JK	JK	JK
Revise manuscript for important intellectual content	JK	JK EH MAM DS	JK IDG WP DKH DS	JK IDG WP DKH DS
Approve final version	JK	JK EH MAM DS DAF	JK IDG WP DKH DS	JK IDG WP DKH DS
Responsible for overall content	JK	JK	JK	JK

Appendices

Appendix A Qualitative Interview Guide

(Practitioner Version)

Good morning/afternoon/evening. My name is Jen Kryworuchko and I am conducting interviews with practitioners and families to learn more about decision making about level of care in the Intensive Care Unit. During the interview, we want to know more about the decisions people make about level of care in Intensive Care Unit, for example decisions about withdrawing or withholding life support and providing comfort care at end of life. We would like you to tell us about experiences you have had with level of care decision-making, a best and a worst experience, if you can. The information will contribute to designing an intervention to support level of care decision-making at the Ottawa Hospital. All of the information we collect in this interview will be kept confidential. We'd like your help; it could take about 30-60 minutes. Once we have interviewed everyone for the study, we will call you for a second interview to get your feedback about our interpretation, which might take 15-30 minutes.

CHARACTERISTICS OF PRACTITIONER

1. Age ____
2. Sex male female
3. Marital Status single married Other _____
4. Education high school college University Masters PhD
5. Practice Specialty
 MD ICU Intensivist MD ICU Fellow MD ICU Resident MD Palliative Care
 RN ICU RN RACE RN Palliative Care
 RT ICU RT RACE
 Social Worker
 Pastoral Care Team
 Volunteer
6. TOH Campus Civic General Both
7. Culture would like to specify

Tell me about a decision about level of care that you were involved in that was really memorable for you...What was the worst decision that you were ever involved in? What was the best decision?

OPTIONAL PROMPTS:

What does level of care mean to you? What are the options for decisions about levels of care?
 What do you see as the advantages and disadvantages of the options?
 Tell me more about your role in making, supporting and implementing level of care decisions.
 How would you describe an excellent quality decision about level of care/at end of life?
 How do patients and their families get involved in making such a decision?

[THANK YOU]

(Patient/Family Version)

Good morning/afternoon/evening. My name is Jen Kryworuchko and I am conducting interviews with practitioners and families to learn more about decision making about level of care in the Intensive Care Unit. We are interested in the decisions to come to ICU to use life support, and decisions about withdrawing or withholding life support and providing comfort care at end of life. We want to be able to give patients and families better support when they are making these types of decisions, and we think that your story will help us. All of the information we collect in this interview will be kept confidential. We'd like your help; it could take about 30-60 minutes. Once we have interviewed everyone for the study, we will call you for a second interview to get your feedback about our interpretation, which might take 15-30 minutes.

CHARACTERISTICS of Patient or Family member

Age _____

Sex male female

Marital Status single married Other _____

Education high school college University University Masters University PhD

Occupation or Profession _____

TOH Campus Civic General Both

Tell me about your family

Structure

Developmental stage

Relationship to patient patient spouse Other _____

Role as key informant regarding this health issue

Culture

Religion and spirituality

Duration of experience with health problem

Do you know what I mean by level of care? How would you define that?

Tell me about your experience with deciding about level of care in the ICU.

[THANK YOU]

Appendix B Decision Aid for Families



**Understanding
the OPTIONS**

Planning care for critically ill patients in the Intensive Care Unit

Understanding *the* OPTIONS

Planning care for critically ill patients in the Intensive Care Unit

Critical illness threatens a patient's life so that they are near death. When a critically ill patient is not capable of making decisions, a family member may be asked to make decisions for them. This person is called a substitute decision maker.

This guide prepares you, as the substitute decision maker, to consider care options for your family member during critical illness. It will help you share your views with other family members and the healthcare team. The plan of care must be discussed with the doctor in charge of your family member's care in the Intensive Care Unit (ICU). The healthcare team will then work together to implement the decision.

Who cares for your family member in the Intensive Care Unit?

Some critically ill patients will receive care in an Intensive Care Unit. Care here is given by a healthcare team which may include nurses, doctors, social workers, pastoral care workers, clinical ethicists, respiratory therapists, pharmacists, physiotherapists, occupational therapists and dietitians.

What types of care are given in the Intensive Care Unit?

The members of the healthcare team work together to discover the reasons for the critical illness and provide care around the clock to treat the problem. This guide presents two types of care that can be given in the ICU: life support and comfort care.

Care Options

At this time, your family member may already be using some kind of life support. Even so, your healthcare team wants to make sure that life support is a treatment you think your family member would want.

LIFE SUPPORT

Life support aims to lengthen life while trying to cure illness. The healthcare team can explain what kinds of life support might be helpful for the patient. It can include the use of a breathing machine as well as drugs and procedures to maintain body functions and minimize suffering. The patient is usually kept asleep.

Reasons to choose this option:

The patient has a better chance of staying alive longer. This may give family members from far away enough time to visit the patient. Some patients may get better during this time.

Reasons to avoid this option:

The patient is attached to machines and tubes. Some patients are agitated or uncomfortable during treatments. Sometimes, despite the healthcare team's best efforts, the patient on life support may still die.



COMFORT CARE

Comfort care aims to relieve suffering and preserve the dignity of the patient who may be dying. There are usually fewer tests, fewer tubes and no life support machines or monitors connected to the patient.

Reasons to choose this option:

The healthcare team can concentrate on relieving the patient's pain and other symptoms with drugs and treatments.

Reasons to avoid this option:

It is likely that, without life support, the critically ill patient's breathing and heart may stop and they may not live as long as they would on life support.



How do I prepare to consider the care options?

Ask yourself the following questions.

STEP 1: What was your family member’s situation before coming to the ICU?

STEP 2: What is your family member’s situation right now?

STEP 3: What matters most to your family member?

STEP 4: Who is involved in this decision?

STEP 5: What else do you need to do to prepare for decision making?



INTRODUCE YOURSELF to your family member’s healthcare team when you meet them at the bedside, or ask the nurse to help arrange a meeting between family and healthcare team members. Use this guide to help you prepare your questions.

STEP 1: What was your family member’s situation before coming to the ICU?

Check how your family member was over the last few weeks before coming to the ICU.

Moving about	Activity	Self care	Eating & drinking	Alertness
<input type="checkbox"/> Able to move about as usual	<input type="checkbox"/> Able to do their usual activities such as job, hobbies, housework	<input type="checkbox"/> Able to do all their personal care such as washing, dressing, going to the bathroom	<input type="checkbox"/> Able to eat and drink as usual	<input type="checkbox"/> Alert as usual
<input type="checkbox"/> Moving about less than usual	<input type="checkbox"/> Able to do their usual activities <i>with effort</i>	<input type="checkbox"/> Needed occasional help with their care	<input type="checkbox"/> Ate and drank less than usual	<input type="checkbox"/> Less alert than usual
<input type="checkbox"/> Mainly sitting	<input type="checkbox"/> Unable to do their usual job	<input type="checkbox"/> Needed a lot of help with their care	<input type="checkbox"/> Ate small amounts of food and sips of fluids	<input type="checkbox"/> Drowsy most of the time
<input type="checkbox"/> Mainly in bed	<input type="checkbox"/> Unable to do their usual hobbies or housework	<input type="checkbox"/> Someone else provided most of their care	<input type="checkbox"/> Not able to eat or drink	<input type="checkbox"/> Slept all of the time
<input type="checkbox"/> In bed all of the time	<input type="checkbox"/> Unable to do any work	<input type="checkbox"/> Someone else provided all of their care		
	<input type="checkbox"/> Unable to do most activities			
	<input type="checkbox"/> Unable to do any activities			

How would you rate your family member’s overall quality of life over the last few weeks before coming to the ICU? Worst possible Poor Fair Good Best possible

STEP 2: What is your family member’s situation right now?

Some serious problems of patients in the ICU are listed below.

Check ✓ if your family member has these problems right now.

	Yes	No	I don't know
Brain injury. Do they have a brain injury that prevents them from waking up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Breathing with help. Do they depend on a machine to breathe?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heart problems. Do they need drugs to keep their blood pressure up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Kidneys don't work. Do they no longer make urine and need a dialysis machine to filter their blood?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Digestion problems. Do they need to be fed by a tube into their bloodstream?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Liver problems. Do they have yellow skin because their liver is not working?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bleeding difficulties. Do they have problems with bruising or bleeding, enough that they need transfusions with blood or platelets?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Severe infection. Do they have a severe infection that affects their blood pressure?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
List any other problems here. _____			

What do you think might be the outcome of your family member’s critical illness?

Your expectations may change as your family member’s health situation changes.

Check ✓ what you expect right now.

- I think that they might be healthier than before they became critically ill.
- I think that they might improve back to the way they were before they became critically ill.
- I think that they might improve, but not be as well as they were before they became critically ill.
- I think that they might improve, but live with serious health losses.
- I think that they might die soon.
- I don't know what might happen.
- Other expectations

STEP 3: What matters most to your family member?

Does your family member have a written document (an advance directive) that includes their wishes for medical care if they are critically ill? Check one Yes No I don't know

Common reasons to choose either life support or comfort care are listed below.

Choose how much you think each reason matters to your family member. Circle your choice on a scale from 0 to 5, where 0 means it is not important to your family member and 5 means it is very important to them.

Reasons to choose life support

How important is it for your family member...	Not important ←————→ Very important					
...to live as long as possible?	0	1	2	3	4	5
...to have more time with family?	0	1	2	3	4	5
...to respect a belief that life should be preserved?	0	1	2	3	4	5
List other reasons your family member would want life support.						
_____	0	1	2	3	4	5
_____	0	1	2	3	4	5

Reasons to choose comfort care

How important is it for your family member...	Not important ←————→ Very important					
...not to prolong their death?	0	1	2	3	4	5
...to be comfortable and suffer as little as possible?	0	1	2	3	4	5
...to avoid being attached to machines and tubes?	0	1	2	3	4	5
...to respect a belief that nature should take its course?	0	1	2	3	4	5
List other reasons your family member would want comfort support.						
_____	0	1	2	3	4	5
_____	0	1	2	3	4	5

Now, think about which option has the reasons that would be most important to your family member. What do you think your family member would want in this situation?

Check one Life support Comfort Care I'm not sure

STEP 4: Who is involved in this decision?

Think about who should be involved in this decision. Your healthcare team, family and friends can provide support as you consider care options for your family member in the ICU. Ask others to share the reasons why they prefer one option.

Name	Relationship to the patient?	Which option does this person prefer? Check ✓ one	How can this person help plan for care in the ICU?
Your name		<input type="checkbox"/> Life support <input type="checkbox"/> Comfort care <input type="checkbox"/> I'm not sure	
ICU doctor		<input type="checkbox"/> Life support <input type="checkbox"/> Comfort care <input type="checkbox"/> I'm not sure	
		<input type="checkbox"/> Life support <input type="checkbox"/> Comfort care <input type="checkbox"/> I'm not sure	
		<input type="checkbox"/> Life support <input type="checkbox"/> Comfort care <input type="checkbox"/> I'm not sure	
		<input type="checkbox"/> Life support <input type="checkbox"/> Comfort care <input type="checkbox"/> I'm not sure	
		<input type="checkbox"/> Life support <input type="checkbox"/> Comfort care <input type="checkbox"/> I'm not sure	

How would you prefer to be involved in decision making?

Check ✓ one.

- I prefer to make the decision about the patient's type of care.
- I prefer that other family members and I make the decision about the patient's type of care.
- I prefer that other family members and I make the decision about the patient's type of care, after seriously considering the healthcare team's opinion.
- I prefer that the healthcare team and family share responsibility for the decision about the patient's type of care.
- I prefer that the healthcare team makes the decision about the patient's type of care, after seriously considering the family's opinion.
- I prefer that the healthcare team makes the decision about the patient's type of care.

STEP 5: What else do you need to do to prepare for decision making?

Yes No

Knowledge

- Do you know enough about your family member’s health situation right now?
- Do you know enough about how your family member is expected to recover?
- Do you know enough about the benefits and risks of each option (comfort care or life support)?

Values

- Are you clear about what matters most to your family member?

Support

- Do you have enough support to participate in decision making?
- Do you have enough advice to participate in decision making?

Certainty

- Do you feel sure about the best decision for your family member?

Understanding *the* OPTIONS PAGE 12

NEXT STEPS

How can I find out more about care in the ICU?

- Make a list of your questions.
- Ask your healthcare team for answers when you are at the bedside.
- Ask to have a family meeting with your healthcare team.

How can I decide what matters most to my family member?

- Review your answers in Step 3.
- Discuss what matters most with other family members.
- Discuss with others how documents written by the patient can be considered in decision making.

How can I share my thoughts with others?

- Share the answers in this guide with your family and healthcare team.
- Talk to the people whose opinions matter most.
- Find someone neutral to help you talk with others. Nurses, social workers and clinical ethicists in hospital settings often help families discuss important decisions like this.

What do you plan to do to prepare for decision making? _____

Since a patient’s health situation often changes in the ICU, you may revisit the decision several times to make sure that your family member continues to receive the care that they would want.

I would like to re-evaluate my family member’s situation on this date. _____

Understanding *the* OPTIONS PAGE 13

Patient name _____ Time _____ Date _____

Your name _____

Notes _____

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Funding source: The Foundation for Informed Medical Decision Making. Authors declared no conflict of interest.
Format is based on the Ottawa Decision Guide © 2000, A. O'Connor, D. Stacey, University of Ottawa, Canada

Table on page 5 is adapted from PPSv2 tool (Anderson et al. 1996; Karnofsky, 1948)
QOL question on page 5 is from MVQOLI (Byock and Merriman, www.dyingwell.org/MVQOLI.htm)
Table on page 6 is simplified from LeGall's criteria, 1982
Table on page 11 is adapted from Degner & Sloan, 1992
Table on page 12 is adapted from Decision Conflict Scale (O'Connor, 1998)

Date: March 2009, Next update due in 2011.



Appendix D Decision Aid Development

Intervention Development

This appendix provides a detailed description of the patient decision aid (DA) intervention “*Understanding the options: Planning for a family member’s care during their critical illness*” and its development prior to field testing. The overall goal of the DA was to structure a family member’s explicit consideration of the decision in preparation for participation in decision-making about life support for their critically ill relative in ICU. The DA was based on the Ottawa DA Template developed by the Patient Decision Aids Research Group (<http://decisionaid.ohri.ca/about.html>), informed by the Interprofessional Shared Decision Making (IP-SDM) model (Legare et al., 2010) and developed to overcome identified barriers to an IP-SDM approach to life support decision-making (Table C.1). It was structured to meet the International Patient DA Standards (IPDAS) (Elwyn et al., 2006) (Table C.2). The guide was written for a lay audience at a Flesch-Kincaid grade 8 reading level (Kincaid, Fishburne, Rogers, & Chissom, 1975).

Four panels of reviewers participated in the development process: 1) shared decision-making experts, 2) healthcare professionals with ICU expertise, 3) editors with experience publishing plain language documents, and 4) community-living adults. Shared decision-making experts were 4 researchers at the Patient DAs Research Group (<http://decisionaid.ohri.ca>) with expertise in developing, formatting, and implementing Patient DAs. Healthcare professionals with ICU expertise were accessed through the Canadian Researchers at End-of-Life Network (CARENET). They included 25 specialty intensivist physicians, residents, nurses, and clinical ethicists who both practiced and conducted research in the ICU setting. The 3 editors who produced the document with the research team have produced plain language documents for low literacy populations and provided helpful advice about the clarity and simplicity of language as well as the layout and flow of the document. Community-dwelling adults were 10 adults between 22 to 65 years who were naïve to decision-making theory but had experience as patients and family members in the healthcare system; some of these adults had experience with a

family member admitted to the ICU. A copy of the DA was sent to these experts for review and their feedback was returned to the research team in person, by teleconference, in writing or in tracked changes to the document.

Expert feedback was received about the layout, flow, language, and overall content. Revisions were discussed with the expert reviewer and then the research team made a decision about whether to revise the decision DA. During the review process, 26 iterations of the DA were produced over a period of ten months. After version 22, the DA underwent minor changes in wording only, and the substantive content of the DA was stabilized. The DA was presented to healthcare professionals in the ICU where it was implemented and reviewed by the hospital Ethics Review Board. No further changes were required by these groups; therefore, at version 26 the DA was considered ready to trial with family members of patients in ICU. The final version of the DA (Appendix B) (<http://decisionaid.ohri.ca/AZsumm.php?ID=1388>) was rated by an independent appraiser at the Patient Decision Aids Research Group using the IPDAS checklist (Elwyn et al., 2006) (Table C.2).

Table C.1 Components of intervention addressing identified barriers to involving families

Potential elements to retain for family involvement in the decision-making process about life support in ICU (Chapter 1)	Identified Barriers to IP-SDM approach to decisions about Life Support (Chapter 3)	Content of the DA
Decision Point: Discuss the nature of the decision, timing, stage of decision-making	<p>Family not being emotionally ready to receive information</p> <p>Desire to avoid burdening family</p> <p>No specific trigger for the process</p>	<p>DA used language so that it could be introduced to family members within 24-48 hours of the patient's admission to ICU.</p> <p>Page 1 introduced the context for the family member's involvement in decision-making: the patient's critical illness and admission to ICU necessitating a decision about life support intervention.</p> <p>Step 1, Page 5 Asked family to reflect on the patient's situation before coming to ICU. The goal of this step was to incorporate the patient's personal circumstances before coming to ICU into the ongoing decision-making process about life support. Questions were adapted from the Palliative Performance Scale version 2 instrument (Anderson, Downing, Hill, Casorso, & Lerch, 1996; Karnofsky, 1948), and The quality of life question from the Missoula-VITAS Quality of Life Index (used with permission, available at www.dyingwell.org/MVQOLI.htm).</p> <p>Step 2, Page 6 Asked family to describe the current situation of the patient. The purpose of step 2 was to help family identify serious health problems the patient was experiencing in ICU, as well as to anchor this understanding within the context of other problems the patient could experience. The questions used lay terms for typical life support technologies that might be used to treat organ failure based on Le Gall's criteria for organ system failure (Le Gall JR, Brun Buisson C, & Trunet P, 1982).</p> <p>Step 2, Page 7 Elicited family's expectations about the patient's recovery so that they could be realigned as necessary by the healthcare team.</p>

<p>Explicitly identify interprofessional roles to support family to deliberate</p>	<p>Inconsistent messages from team</p>	<p>Page 4 describes five step process intended to facilitate reflection on what they know and how they can find out more from healthcare professionals in order to engage in the decision-making process about life support for the critically ill patient in ICU.</p>
<p>Include professionals and others identified by family to ensure relevant input on the decision</p>		
<p>Present options including alternatives</p>	<p>Not including alternative options</p>	<p>Pages 2 and 3 identify two options for care offered in ICU: life support and its alternative, comfort care.</p>
<p>Discuss for each option the potential benefits, risks, costs, potential outcomes</p>	<p>Not understanding information</p>	<p>Pages 2 and 3 describe options using plain language. Written for a lay audience at a Flesch-Kincaid grade 8 reading level (Kincaid et al., 1975)</p>
<p>Healthcare team collaborates to support/coach family involvement</p>	<p>Lack of interprofessional collaboration Lack of therapeutic relationship with family</p>	<p>DA intended to identify family needs and prepare family for further discussion with healthcare team in ICU. Two strategies identified to enhance DA delivery: 1) Decision coaching: an individualized, non-directive approach used to prepare family members for making decisions with their healthcare team (Stacey, Legare, & Kryworuchko, 2009). The decision coach highlighted the family’s decision-making needs and resources in the following ways: evaluated and promoted readiness to engage in the decision-making process, promoted further dialogue with the family member’s about their understanding of the options, provided opportunities to ask questions and clarify expectations, promoted further dialogue about patient’s and family member’s values regarding the options, and assist family members to meet identified needs in order to progress in decision-making. 2) Decision summary report: synthesized responses provided by family member(s) to the family decision DA in one page (Appendix C). The one pager was based on the format of the decision summary used to implement a patient DA for patients with osteoarthritis considering hip or knee replacement (Stacey et al., 2008).</p>

<p>Assess family’s understanding of decision and decision-making needs</p>	<p>Families not knowing what questions to ask</p>	<p>Page 4 Passage encouraging family members to use the questions in the guide to develop their own questions for their healthcare team</p> <p>Step 5, Page 12 and 13 Evaluates the family’s progress in decision-making Step 5 of the DA was followed by a list of suggestions to help family members identify “next steps” in decision-making and the healthcare professionals most suited to providing targeted support for identified issues. Questions included were adapted from the Decision Conflict Scale similar to the SURE test for clinical practice describing several modifiable factors contributing to uncertainty in decision-making (O’Connor, 1995; Legare & et.al., 2010). The tool is used as a clinometric tool to identify decision needs: items answered “no” may reflect a need for targeted support in decision-making.</p>
<p>Elicit and clarify patient’s values and explore influence of other stakeholders’ values</p>	<p>Different values among family members driving preferences</p> <p>Dominant influence of professionals’ values</p>	<p>Step 3, Page 8 and 9 Engaged family to identify and share what was known about the patient’s values to ensure that they could have a central place in the decision-making process. Then asked if the patient had made an advanced directive or expressed wishes that should be considered in the decision-making process.</p> <p>A structured set of values was provided to help the family reflect on the patient’s previously stated values and preferences. Included values were drawn from The End-of-life Values Scale (Winter & Parks, 2008), broad literature about values important at end-of-life, and perspectives of families and healthcare professionals about values influencing the decision about life support (Chapter 3). Finally, recognizing that the values that were included were not exhaustive, there was space for family members to add other values that they considered important to the patient.</p>
<p>Assist patient/family to construct preference</p>	<p>Being unclear about patient wishes</p>	<p>Step 3, Page 9 Asked family member to identify patient’s preferred option after values clarification</p>
<p>Explore preferred option: feasibility, timing, impact of the decision / potential outcomes</p>		<p>Step 5, Page 13 Asks family to identify date to re-evaluate situation. DA intended to prepare family for further discussion with healthcare team in ICU.</p>
<p>Discuss uncertainty in the information</p>	<p>Asymmetry of power</p>	<p>Explicitly recognizing the domains where family input is invaluable (sharing important information about previous health, response to treatments and values) to reinforce the central role of family in</p>

provided; Physician recommends an option; Discuss important disagreement/ uncertainty regarding recommendations

health decision-making for critically ill patients

Reach agreement about the option: to use, withhold or withdraw life support for the critically ill patient in ICU	Difficulty reaching agreement	<p>Step 4, Page 10 Asks family to think about other people involved in the patient’s life and how their perspectives might affect the present decision-making process about life support for the critically ill patient.</p> <p>Step 4, Page 11 Asks family members to choose between five statements about their preferred level of involvement in healthcare decision-making. As a result, healthcare professionals can engage family in their ‘preferred ways’ in the decision-making process, specifically at the choice stage where involvement is perceived as particularly burdensome. Statements regarding family’s preferred role in the decision-making process were adapted from Preference for Role in Decision Making Scale adapted from Degner & Sloan’s work with decision-making in health care (Degner & Sloan, 1992). This adapted version was used in other studies of family caregivers in ICU (Heyland et al., 2003).</p>
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Table C.2 IPDAS Checklist

Content	Answer
1. The DA describes the condition (health or other) related to the decision.	Yes
2. The DA describes the decision that needs to be considered (the index decision).	Yes
3. The DA lists the options (health care or other).	Yes
4. The DA describes what happens in the natural course of the condition (health or other) if no action is taken.	Yes
5. The DA has information about the procedures involved (e.g. what is done before, during, and after the health care option).	Yes
6. The DA has information about the positive features of the options (e.g. benefits, advantages).	Yes
7. The DA has information about negative features of the options (e.g. harms, side effects, disadvantages).	Yes
8. The information about outcomes of options (positive and negative) includes the chances they may happen.	NA
9. The DA has information about what the test is designed to measure.	NA
10. The DA describes possible next steps based on the test results.	NA
11. The DA has information about the chances of disease being found with and without screening.	NA
12. The DA has information about detection and treatment of disease that would never have caused problems if screening had not been done.	NA
13. The DA presents probabilities using event rates in a defined group of people for a specified time.	NA
14. The DA compares probabilities (e.g. chance of a disease, benefit, harm, or side effect) of options using the same denominator.	NA
15. The DA compares probabilities of options over the same period of time.	NA
16. The DA uses the same scales in diagrams comparing options.	NA
17. The DA asks people to think about which positive and negative features of the options matter most to them.	Yes
18. The DA makes it possible to compare the positive and negative features of the available options.	Yes
19. The DA shows the negative and positive features of the options with equal detail.	Yes
Development Process	Answer
20. Users (people who previously faced the decision) were asked what they need to prepare them to discuss a specific decision.	Yes
21. The DA was reviewed by people who previously faced the decision who were not involved in its development and field testing.	Yes
22. People who were facing the decision field tested the DA.	Yes
23. Field testing showed that the DA was acceptable to users (the general public & practitioners).	Yes

24. Field testing showed that people who were undecided felt that the information was presented in a balanced way.	Yes
25. The DA provides references to scientific evidence used.	Yes
26. The DA reports the date when it was last updated.	Yes
27. The DA reports whether authors of the DA or their affiliations stand to gain or lose by choices people make after using the DA.	Yes
28. The DA (or available technical document) reports readability levels.	Yes
Effectiveness	Answer
29. There is evidence that the DA (or one based on the same template) helps people know about the available options and their features.	Unknown
30. There is evidence that the DA (or one based on the same template) improves the match between the features that matter most to the informed person and the option that is chosen.	Unknown

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- Stacey, D., Legare, F., & Kryworuchko, J. (2009). Evidence-based healthcare: Roles for health professionals. In G.Elwyn & A. Edwards (Eds.), *Evidence-based shared decision making in health care: achieving evidence based patient choice* (2 ed., pp. 29-35). Oxford, UK: Oxford University Press.



Appendix E Consent Forms



Information Sheet and Consent Form

Université d'Ottawa
Faculté des sciences
de la santé
École des sciences
infirmières

University of Ottawa
Faculty of Health
Sciences
School of Nursing

Development and evaluation of an intervention to engage interprofessional healthcare teams, patients and families in shared decision making about the level of care in the Intensive Care Unit - Phase 3: Feasibility Study

Research Team

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Introduction

You are being asked to participate in this research study because you are the family member or healthcare provider of a patient admitted to the Intensive Care Unit.

Please read this Patient Information Sheet and Consent form carefully and ask as many questions as you like before deciding whether to participate in this research study. You can discuss this decision with your family, friends and your healthcare team.

Background, Purpose and Design of the Study

Admission to the intensive care unit ICU is a difficult time for families and patients. Sometimes it is overwhelming. We would like to better understand how we can help our patients and their families make quality decisions about their level of care in the intensive care unit. Level of care refers to establishing guidelines for the care we provide – from “do everything” to “withdraw life support and provide comfort care only”.

This study is a continuation of a previous study. We interviewed family members and healthcare providers in ICU to describe decision making about level of care in the intensive care unit (ICU). From that research, we designed an intervention to help families participate in decisions about level of care in the Intensive Care Unit (ICU) with healthcare team members. Now, we would like to get feedback from family members and healthcare providers about the intervention.

Study procedures

As a study participant, we will ask you to participate in the intervention. It has three parts: (1) the decision support guide for family members (2) the decision summary report; and (3) a short explanation for the healthcare team member who will act as a resource person to the family while they complete the guide.

Also, we will ask participants to (1) Complete two questionnaires, (2) Give permission to the research team to observe and/or audiotape family conferences, and (3) Participate in a 15 minute interview. The questionnaires will be given once before and once after the intervention. We will ask you questions about the acceptability of the intervention, family member distress (family member participants only), preparation to become involved in decision making, involvement in the decision making process, and some demographic data. You may skip any questions that you do not feel comfortable answering. Data collection sessions will be arranged with the researcher at a location that is convenient for you.

Study Duration

Participating in the study may take a total of 1 hr 45 min over a three day period.

Possible Side Effects or Risks

Rarely, some people may find it difficult or upsetting to talk about decision making about the level of care. This might happen even if you did not participate in this study.

The healthcare team in ICU is available to provide support; as well, we encourage you to use

your usual support network of friends, family, and meet with your family doctor if you are very upset. Employee Assistance Program offers further counseling to staff.

Benefits of the Study

You may not receive any direct benefit from your participating in this study. Your participation in this research may allow the researchers to contribute to knowledge of how to best support families who are deciding about level of care in ICU, which may be of benefit to future patients and families.

Withdrawal from the Study

Your participation in this study is voluntary. You can stop data collection or withdraw from the study at any time. Such withdrawal will be treated as confidential by the research team. Deciding to participate, or not to participate, in this research will not affect the care you receive as a family member or your job as a healthcare provider. You can choose to let researchers use the data that was collected OR destroy all data that was collected, however, if you withdraw, no further data will be collected. Information already shared with the healthcare team as part of this study may still be used by the healthcare team to prepare for discussions with family members.

Compensation

In the event of research-related injury or illness, you will be provided with appropriate medical treatment/care. You are not waiving your legal rights by agreeing to participate in this study. The researchers, healthcare professionals in ICU and the hospital still have their legal and professional responsibilities.

Study Costs

You will not be paid to participate in this research study.

Confidentiality

All personal health information will be kept confidential, unless release is required by law. Due to the nature of the intervention the family member(s) responses to the guide will be made available only to the healthcare team directly involved in the patient and family's care and treatment in ICU and the research team (PI/RA staff).

Representatives of the Ottawa Hospital Research Ethics Board, the Ottawa Hospital Research Institute, as well as the University of Ottawa Research Ethics Board may review your original medical records under the supervision of J. Kryworuchko's staff for audit purposes.

You will not be identifiable in any publications or presentations resulting from this study. No identifying information will leave the Ottawa Hospital. All information which leaves the hospital will be coded with an independent study number.

The link between your name and the independent study number will only be accessible by J. Kryworuchko /or her staff. The link and study files will be stored separately and securely. Both

files will be kept for a period of 15 years after the study has been completed. All paper records will be stored in a locked file and/or office. All electronic records will be stored at the Nursing Best Practice Research Unit at the University of Ottawa and protected by a user password, again only accessible by J. Kryworuchko and/or her staff. At the end of the retention period, all paper records will be disposed of in confidential waste or shredded, and all electronic records will be deleted. Audiotapes will be transcribed and then stored and destroyed in the same manner as other study information.

Voluntary Participation

Your participation in this study is voluntary. If you choose not to participate, your decision will not affect the care you receive at this Institution at this time, or in the future. You will not have any penalty or loss of benefits to which you are otherwise entitled to.

New Information about the Study

You will be told of any new findings during the study that may affect your willingness to continue to participate in this study. You may be asked to sign a new consent form.

Questions about the Study

The principal researcher and the research team are available to answer your questions about the study. If you have any questions about this study or if you feel that you have experienced a research-related injury, please contact Jennifer Kryworuchko at ____.

The Ottawa Hospital Research Ethics Board (OHREB) has reviewed this protocol. The OHREB considers the ethical aspects of all research studies involving human subjects at The Ottawa Hospital. If you have any questions about your rights as a research subject, you may contact the Chairperson of the Ottawa Hospital Research Ethics Board at ____.

Consent Form

Development and evaluation of an intervention to engage interprofessional health care teams, patients and families in shared decision making about the level of care in the Intensive Care Unit

Consent to Participate in Research

I understand that I am being asked to participate in a research study about a decision support intervention for families and healthcare team members deciding about the level of care in the Intensive Care Unit (ICU) setting. This study has been explained to me by Jennifer Kryworuchko, or her delegate.

I have read this 5 page Patient Information Sheet and Consent Form (or have had this document read to me). All my questions have been answered to my satisfaction. If I decide at a later stage in the study that I would like to withdraw my consent, I may do so at any time.

I voluntarily agree to participate in this study.

A copy of the signed Information Sheet and/or Consent Form will be provided to me.

Signatures

Participant's Name (Please Print)

Participant's Signature

Date

Investigator Statement (or Person Explaining the Consent)

I have carefully explained to the research participant the nature of the above research study. To the best of my knowledge, the research participant signing this consent form understands the nature, demands, risks and benefits involved in participating in this study. I acknowledge my responsibility for the care and well being of the above research participant, to respect the rights and wishes of the research participant, and to conduct the study according to applicable Good Clinical Practice guidelines and regulations.

Name of Investigator/Delegate (Please Print)

Signature of Investigator/Delegate

{Valid until May 11, 2011}



Feuille de renseignements et formulaire de consentement

Développement et évaluation d'une intervention pour engager les équipes de professionnels de la santé, les patients et leurs familles dans une prise de décision partagée concernant le niveau de soins prodigués pendant leur séjour aux soins intensifs. Phase 3 : Étude de faisabilité

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Introduction

On vous invite à prendre part à cette étude, car vous êtes membre de famille ou de l'équipe professionnelle d'un patient actuellement aux soins intensifs.

Veillez prendre le temps de lire les renseignements ci-dessous pour en apprendre plus à propos de l'étude avant de décider si vous voulez participer dans l'étude. Pour plus d'information, n'hésitez pas à poser des questions. Discutez-en avec votre famille, vos amis et vos professionnels de la santé.

Fond, But et Méthodologie

L'équipe professionnelle aux soins intensifs, avec les patients et leurs familles, doit prendre des décisions au sujet du niveau de soins prodigués aux patients gravement malades. Ces décisions peuvent être particulièrement difficiles si la décision est d'arrêter ou de maintenir les mesures de soutien vital par exemple.

Nous avons effectué des entretiens avec des membres de famille et l'équipe professionnelle aux soins intensifs dans la première partie de cette étude pour mieux comprendre la prise de décision de niveau de soin pour un patient aux soins intensifs. Par la suite, nous avons développé une intervention pour engager les équipes de professionnels de la santé, les patients et leurs familles dans une prise de décision partagée concernant le niveau de soins prodigués pendant leur séjour aux soins intensifs. Maintenant, nous voudrions essayer cette intervention avec des familles et l'équipe professionnelle aux soins intensifs.

Procédures de l'étude

Si vous acceptez de participer à l'étude, nous vous demandons d'assister à l'intervention dans le cadre de trois étapes (1) un guide pour familles (2) un sommaire et (3) une explication courte pour le professionnel aux soins qui est prêt à soutenir la famille pendant qu'ils complètent le guide.

Par la suite, nous vous demandons de (1) remplir deux questionnaires, (2) donner la permission d'observer et/ou d'enregistrer des réunions avec les familles et l'équipe des soins intensifs, et (3) d'assister dans un entretien avec un chercheur qui pourra prendre 15 minutes. Les questionnaires seront demandés avant et ensuite après l'intervention. Nous posons des questions selon l'acceptabilité de l'intervention, votre détresse (pour les membres de famille), votre préparation et votre engagement dans la discussion de la décision concernant le niveau de soins prodigués pour un patient pendant leur séjour aux soins intensifs. Pendant cet entretien, vous partagerez votre expérience de la prise de décision concernant le niveau de soins pour un patient aux soins intensifs selon votre perspective. Vous avez toujours le droit de ne pas répondre aux questions ou de mettre fin à votre participation à n'importe quel moment au cours de l'étude. Les questionnaires et l'entretien seront conduits dans un local à votre convenance.

Durée de l'étude

L'étude prendra environ 1 h 45, répartie sur 3 jours.

Risques et inconvénients potentiels

Quelques participants peuvent être émotifs ou exprimer de la difficulté à parler de la prise de décision concernant le niveau de soins. L'équipe de soins aux soins intensifs est disponible pour vous aider. Aussi, nous vous encourageons à utiliser le soutien de votre réseau habituel d'amis et de famille, et à prendre rendez-vous avec votre médecin de famille si vous ressentez un niveau de stress trop élevé. Le programme d'aide aux employés peut conseiller les employés de L'Hôpital.

Avantages potentiels de la participation

Votre participation à cette étude contribuera à augmenter les connaissances concernant la meilleure façon de soutenir les familles qui doivent prendre des décisions concernant le niveau de soin à prodiguer à l'unité de soins intensifs. Vous pourriez également ressentir un certain soulagement à parler de ce sujet.

Sortir de l'étude

Votre participation à ce projet est complètement volontaire. Si vous décidez de participer, vous avez le droit de poser aux chercheurs des questions concernant l'étude et ce, à tout moment. Vous n'êtes pas tenu de répondre aux questions qui vous rendent mal à l'aise. Vous avez également le droit de vous retirer de l'étude en tout temps. Votre décision de participer ou non n'influencera pas la qualité des soins que vous et/ou votre famille recevrez à l'unité des soins intensifs. Si vous êtes un employé de L'Hôpital, le fait de participer ou non n'aura aucune implication sur votre emploi ou vos progrès pédagogiques. Si vous préférez de sortir de l'étude, vous pouvez choisir de permettre l'utilisation de vos données ou bien de demander que vos documents papier soient déchiquetés, et les fichiers électroniques soient supprimés de façon permanente sans qu'ils soient utilisés. Toute information déjà partagée avec l'équipe de soins intensifs pourra toutefois être utilisée en vue de rencontres avec votre famille.

Indemnisation

En cas de blessures liées à la recherche ou de maladie, vous pourrez bénéficier d'un traitement médical / soins appropriés. Vous ne renoncez pas à vos droits légaux en acceptant de participer à cette étude. Les chercheurs, professionnels de la santé et aux soins intensifs de l'hôpital ont toujours leurs responsabilités légales et professionnelles.

Frais d'étude

Il n'y a aucune compensation financière associée à votre participation à cette étude.

La confidentialité

Tous les renseignements recueillis dans le cadre de l'étude sont et demeureront confidentiels, à moins que cette divulgation soit requise par la loi. L'équipe de recherche aura accès aux dossiers de recherche, ainsi que les organisations suivantes pour vérification : les Conseils d'éthique en

recherches de L'Hôpital d'Ottawa et de l'Université d'Ottawa et l'Institut de recherche de l'Hôpital d'Ottawa.

En raison de la nature de l'intervention, les réponses de la famille à ce guide seront disponibles seulement à l'équipe de recherche et l'équipe de santé intervenant directement au niveau des soins du patient et de la famille pendant leur séjour aux soins intensifs.

Toute information qui pourrait vous identifier sera supprimée de l'ensemble des données écrites ou des enregistrements et des transcriptions de l'entretien. Nous utiliserons à la place de votre nom un numéro d'étude indépendant. Si les résultats de l'étude sont publiés, votre nom ne sera pas associé aux données présentées. Votre participation à la recherche demeurera confidentielle.

Les renseignements recueillis seront conservés dans un cabinet fermé à clé dans le bureau de la chercheuse principale à l'université d'Ottawa et sur un ordinateur protégé par mot de passe. Les renseignements recueillis seront conservés pendant 15 ans; par la suite, les documents papier seront déchiquetés, et les fichiers électroniques seront supprimés de façon permanente.

Participation volontaire

Votre participation à ce projet est complètement volontaire. Vous avez également le droit de vous retirer de l'étude en tout temps. Votre décision de participer ou non n'influencera pas la qualité des soins que vous et/ou votre famille recevrez à l'unité des soins intensifs. Si vous êtes un employé de L'Hôpital, le fait de participer ou non n'aura aucune implication sur votre emploi ou vos progrès pédagogiques.

Nouveaux renseignements sur l'étude

Vous serez informé de toute conclusion nouvelle au cours de l'étude qui serait susceptible d'influer sur votre volonté de continuer à participer à cette étude. Vous pourriez être invité à signer un nouveau formulaire de consentement.

Pour de plus amples renseignements

La chercheuse principale et les membres de l'équipe de recherche sont disponibles pour répondre à vos questions concernant l'étude. Si vous avez des questions ou si vous croyez que vous souffrez dans le cadre de votre participation à l'étude, veuillez communiquer avec Jennifer Kryworuchko, au ____.

Le Conseil d'éthique en recherches de L'Hôpital d'Ottawa (CÉRHO) a examiné le présent protocole. Le CÉRHO examine les aspects éthiques de toutes les recherches portant des sujets humains à L'Hôpital d'Ottawa. Si vous avez des questions concernant vos droits en tant que participant à une recherche, vous pouvez communiquer avec le président du Conseil d'éthique en recherches de L'Hôpital d'Ottawa, au ____.

Développement et évaluation d'une intervention pour engager les équipes de professionnels de la santé, les patients, et leurs familles dans une prise de décision partagée concernant le niveau de soins prodigués pendant leur séjour aux soins intensifs.

Consentement de participation à la recherche

Je reconnais que je suis invité à participer à une étude de recherche sur une intervention pour engager les familles et les membres de l'équipe soignante dans une prise de décision partagée concernant le niveau de soins prodigués pendant leur séjour aux soins intensifs. Cette étude m'a été expliquée par Jennifer Kryworuchko, ou sa délégué.

J'ai lu cette feuille de renseignements et formulaire de consentement de 5 pages (ou bien quelqu'un l'avait lu à haute voix). J'ai reçu des réponses satisfaisantes à toutes mes questions. Je reconnais que je puis mettre fin à ma participation à l'étude en tout temps.

J'accepte volontairement de participer à cette étude.

On me remettra une exemplaire du document d'information signé et/ou du formulaire de consentement.

Signatures

Nom du participant (en lettres moulées)

Signature du participant

Date

Déclaration de la chercheuse (ou de la personne expliquant la procédure de consentement)

J'ai soigneusement expliqué au participant à la recherche de la nature de l'étude de recherche ci-dessus. Pour autant que je sache, le participant qui signe ce formulaire de consentement comprend la nature, les exigences, les risques et les avantages de participer à cette étude. Je reconnais ma responsabilité relative aux soins et au bien-être du participant à la recherche ci-dessus, et au respect des droits et des souhaits du participant à la recherche, et au déroulement de l'étude conformément aux directives et aux règlements relatifs à la bonne pratique clinique.

Nom de la chercheuse / du délégué (en lettres moulées)

Signature de la chercheuse / du délégué

{Valide jusqu'au 11 mai 2011}

Appendix F Decision Coaching

Decision Coaching

The inclusion of the decision coach role in the delivery of the DA was intended to address barriers to engaging families in the decision-making process. Decision coaching is an individualized, non-directive approach used to prepare family members for making decisions with their healthcare team (Stacey, Legare, & Kryworuchko, 2009). Many individuals have developed the skills required to successfully provide decision coaching to patients and families; in other research studies this role has been filled by nurses (Kennedy et al., 2002; Lerman et al., 1997; Rothert, Holmes-Rovner, Rovner, & Jill Kroll, 1997; Stacey, Taljaard, Drake, & O'Connor, 2008; Stacey, Chambers, Jacobsen, & Dunn, 2008; Stacey et al., 2008), pharmacists (Murray, 2009), counselors (Green, Biesecker, McInerney, Mauger, & Fost, 2001; Lerman et al., 1997; Murray, 2009), psychologists (Rothert et al., 1997), health educators (Myers et al., 2005), and university students (Belkora, Franklin, O'Donnell, Ohnemus, & Stacey, 2009). In this study, it was felt that healthcare professionals identified as providing a support role in ICU (Chapter 3) would also be particularly suited to providing decision coaching; these professionals included mid level or resident physicians, nurse practitioners, critical care nurses, respiratory therapists, social workers, pastoral care workers, and clinical ethicists. Since the ICU presented challenges for taking staff away from the bedside to attend workshops or training, willing decision coaches were identified by the ICU leadership and then individually provided with a short explanation of the DA and coaching role instead of using a coaching tutorial, or a workshop as in other implementation studies (Murray, O'Connor, Stacey, & Wilson, 2008; Stacey, Pomey, O'Connor, & Graham, 2006).

Particularly relevant to this study, barriers such as family members not being emotionally ready and healthcare professionals desire to avoid burdening family might be addressed by the coach providing individualized targeted support. Indeed, this individualized support seemed to be a key feature that resulted in decreased stress, anxiety and depression in families (Lautrette et al., 2007). While many of the reported barriers would be addressed primarily by the DA, it was felt that individualized support

would enhance the impact of the DA given the sensitivity of the decision about life support. There is support for the idea that family involvement in decision making can be reinforced by the presence of a member of the healthcare team functioning in a decision coaching role (Legare et al., 2010; O'Connor, Stacey, & Legare, 2008; Stacey et al., 2008). For example, a decision coach might help families with difficulty understanding information by helping family members identify questions and cue the healthcare team to provide understandable information. Patient DAs which included coaching improved knowledge compared to usual care (Green et al., 2001; Hamann et al., 2006; Legare & et.al., 2010; Lerman et al., 1997).

Key decision coaching role competencies met by healthcare professionals providing coaching are described in Table D.1 (Myers, 2005; Stacey et al., 2008; Woolf et al., 2005). To deliver the life support DA for families in ICU, it was considered important that the decision coach developed a supportive relationship with family members and facilitated preparation for SDM. The decision coach identified themselves to family members and provided them with the family decision DA. The decision coach helped family members work through the steps of the DA as needed. The coach encouraged family members to respond to the questions that established baseline information about the family's progress in decision-making and encouraged them to develop a list of questions for their healthcare team. Once the family completed the DA and the decision summary report was generated, then either the decision coach or family members shared the summary with the healthcare team in ICU. Specifically, the decision coach highlighted the family's decision-making needs and resources in the following ways: evaluated and promoted readiness to engage in the decision-making process, promoted further dialogue with the family member's about their understanding of the options, provided opportunities to ask questions and clarify expectations, promoted further dialogue about patient's and family member's values regarding the options, and assist family members to meet identified needs in order to progress in decision-making.

Table D.1 Characteristics of Decision Coaching

Decision Coaching Element	ICU Context
Coach's discipline	Critical Care Nursing
Type of coaching	In person
Length of time (min)	15-75 min
Assess/discuss pt's decision making needs	✓
Provide information (e.g. options, benefits, harms)	✓
Assess understanding	✓
Clarify values	✓
Build skills in deliberation, communication, and accessing support	✓
Monitor/facilitate progress in DM	✓
Screen for implementation needs	N/A
Total number elements	6

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Appendix G Field Testing Questionnaires

(Family Member) Time 1 Questionnaire (Enrolment)

What was your family member's health status, in the weeks before they became critically ill?

Excellent Very good Good Fair Poor

Please answer these questions about yourself.

1. What is your relationship to the patient?
 Spouse Partner Child Parent Sibling
 Friend Healthcare provider Other, specify _____
2. Are you the legal surrogate decision-maker for this patient? Yes No Unsure
3. How old are you? _____ years.
4. Sex male female
5. What is your marital status?
 a. never married married widowed divorced Other

6. What is your highest level of education?
 Elementary Some high school High School
 College University Masters PhD
7. What is your occupation or profession? _____
8. What is your health status? Excellent Very good Good Fair Poor

How do you prefer to be involved in decision making?

This tool asks about roles deciding about type of care. Answer from *your point of view* by putting a tick in one box only.

- I prefer that family make the decision about which type of care the patient will receive.
- I prefer that family make the final decision about the patient's type of care after seriously considering the doctor's opinion.
- I prefer that the doctor and family share responsibility for deciding which type of care is best for the patient.
- I prefer that the doctor makes the final decision about which type of care will be used but seriously considers the family's opinion.
- I prefer to leave all decision regarding the patient's type of care to the doctor.

How are you feeling?

Indicate how frequently each of these comments was true for you during the past seven days while your family member was a patient in the ICU. Circle the number that shows how much you agree with each statement.

	Not at all	Rarely	Sometimes	Often
1. I thought about it when I didn't mean to.	0	1	3	5
2. I avoided letting myself get upset when I thought about it or was reminded of it.	0	1	3	5
3. I tried to remove it from memory.	0	1	3	5
4. I had trouble falling asleep or staying asleep because of thoughts about it that came into my mind.	0	1	3	5
5. I had waves of strong feelings about it.	0	1	3	5
6. I had dreams about it.	0	1	3	5
7. I stayed away from reminders of it.	0	1	3	5
8. I felt as if it hadn't happened or wasn't real.	0	1	3	5
9. I tried not to talk about it.	0	1	3	5
10. Pictures about it popped into my head.	0	1	3	5
11. Other things kept making me think about it.	0	1	3	5
12. I tried not to think about it.	0	1	3	5
13. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	3	5
14. Any reminder brought back feelings about it.	0	1	3	5
15. My feelings about it were kind of numb.	0	1	3	5

Impact of Event Scale From Horowitz, Alvarez, Wilner, 1979 and Horowitz, 2004
http://www.mardihorowitz.com/impact_of_events_scale

How prepared do you feel to participate in decision making?

Think about the information and support that you have received to help you decide about the type of care for the patient in ICU. Type of care decisions include decisions to use life support, or decisions to withhold or withdraw life support and focus on comfort care. Circle the number that shows how much you agree with each statement.

Did this information and support:	Not at all	A little	Some-what	Quite a bit	A great deal
1. Help you recognize that a decision needs to be made?	1	2	3	4	5
2. Prepare you to make a better decision?	1	2	3	4	5
3. Help you think about the pros and cons of each option?	1	2	3	4	5
4. Help you think about which pros and cons are most important?	1	2	3	4	5
5. Help you know that the decision depends on what matters most to the patient?	1	2	3	4	5
6. Help you organize your own thoughts about the decision?	1	2	3	4	5
7. Help you think about how involved you want to be in the decision?	1	2	3	4	5
8. Help you identify questions you want to ask the ICU team?	1	2	3	4	5
9. Prepare you to talk to the ICU team about what matters most to you?	1	2	3	4	5
10. Prepare you for a family meeting with the ICU team?	1	2	3	4	5

©Preparation for Decision Making Scale (Graham, O'Connor 1996, revised 2005) University of Ottawa

How much are you involved in decision making about type of care for the patient in ICU?

Please answer every question from *your point of view* by putting a tick in one box only for each question.

1. A health problem was identified, where it was made clear that a decision was needed.	Strongly Agree	Agree	Disagree	Strongly Disagree
2. More than one way to manage the health problem was described.	Strongly Agree	Agree	Disagree	Strongly Disagree
3. Different sources of information (e.g. leaflets, websites, contact with other people) to help make the decision were offered.	Strongly Agree	Agree	Disagree	Strongly Disagree
4. Different options (including the possibility of doing nothing) were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
5. The advantages, disadvantages and possible outcomes of options were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
6. Ideas or expectations about managing the health problem were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
7. Concerns or worries about managing the health problem were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
8. It was made sure that information had been understood.	Strongly Agree	Agree	Disagree	Strongly Disagree
9. There were opportunities to ask questions.	Strongly Agree	Agree	Disagree	Strongly Disagree
10. The preference to take part in the decision (or not) was respected.	Strongly Agree	Agree	Disagree	Strongly Disagree
11. During the consultation, a decision was made; or there was an agreement to postpone making the decision.	Strongly Agree	Agree	Disagree	Strongly Disagree
12. The possibility of coming back to the decision was discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree

(Family Member) Time 2 Questionnaire

What did you think about the guide called Planning care for critically ill patients in the Intensive Care Unit?

Please check one answer for each question.

1. Did you read the entire guide?

- Yes
- No

2. Did you use the summary report?

- Yes
- No

3. Did anyone else (such as family or friends) read the guide for family?

- Yes Who: _____
- No

4. Did anyone else review the summary report?

- Yes Who: _____
- No

5. How would you rate the amount of information in the guide?

- Much less than I needed
- A little less than I needed
- About the right amount
- A little more than I needed
- A lot more than I needed

6. How balanced was the guide's information about type of care in ICU?

- Clearly slanted towards **life support treatments (such as a breathing machine)**
- A little slanted towards **life support treatments**
- Completely balanced
- A little slanted towards **comfort care (or treatments that focus on relieving pain and other problems)**
- Clearly slanted towards **comfort care**

7. How clear was the information in the guide?

- Everything was clear
- Most things were clear
- Some things were clear
- Many things were unclear

8. How helpful is the guide in helping you make decisions about treatment options?

- Very helpful
- Somewhat helpful
- A little helpful
- Not helpful

9. Would you recommend this guide to other people who are considering care options for a family member during critical illness?

- I would definitely recommend it
- I would probably recommend it
- I would probably not recommend it
- I would definitely not recommend

10. Overall, how would you rate the guide?

- Poor
- Fair
- Good
- Very good
- Excellent

Acceptability © FIMDM 2009 (Barry 1995, Sepucha 2009)

How prepared do you feel to participate in decision making?

Think about the information and support that you have received to help you decide about the type of care for the patient in ICU. Type of care decisions include decisions to use life support, or decisions to withhold or withdraw life support and focus on comfort care. Circle the number that shows how much you agree with each statement.

Did this information and support:	Not at all	A little	Some-what	Quite a bit	A great deal
1. Help you recognize that a decision needs to be made?	1	2	3	4	5
2. Prepare you to make a better decision?	1	2	3	4	5
3. Help you think about the pros and cons of each option?	1	2	3	4	5
4. Help you think about which pros and cons are most important?	1	2	3	4	5
5. Help you know that the decision depends on what matters most to the patient?	1	2	3	4	5
6. Help you organize your own thoughts about the decision?	1	2	3	4	5
7. Help you think about how involved you want to be in the decision?	1	2	3	4	5
8. Help you identify questions you want to ask the ICU team?	1	2	3	4	5
9. Prepare you to talk to the ICU team about what matters most to you?	1	2	3	4	5
10. Prepare you for a family meeting with the ICU team?	1	2	3	4	5

©Preparation for Decision Making Scale (Graham, O'Connor 1996, revised 2005) University of Ottawa

How much are you involved in decision making about type of care for the patient in ICU?

Please answer every question from *your point of view* by putting a tick in one box only for each question.

1. A health problem was identified, where it was made clear that a decision was needed.	Strongly Agree	Agree	Disagree	Strongly Disagree
2. More than one way to manage the health problem was described.	Strongly Agree	Agree	Disagree	Strongly Disagree
3. Different sources of information (e.g. leaflets, websites, contact with other people) to help make the decision were offered.	Strongly Agree	Agree	Disagree	Strongly Disagree
4. Different options (including the possibility of doing nothing) were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
5. The advantages, disadvantages and possible outcomes of options were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
6. Ideas or expectations about managing the health problem were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
7. Concerns or worries about managing the health problem were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
8. It was made sure that information had been understood.	Strongly Agree	Agree	Disagree	Strongly Disagree
9. There were opportunities to ask questions.	Strongly Agree	Agree	Disagree	Strongly Disagree
10. The preference to take part in the decision (or not) was respected.	Strongly Agree	Agree	Disagree	Strongly Disagree
11. During the consultation, a decision was made; or there was an agreement to postpone making the decision.	Strongly Agree	Agree	Disagree	Strongly Disagree
12. The possibility of coming back to the decision was discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree

How are you feeling?

Indicate how frequently each of these comments was true for you during the past few days while your family member was a patient in the ICU.

Circle the number that shows how much you agree with each statement.

	Not at all	Rarely	Sometimes	Often
1. I thought about it when I didn't mean to.	0	1	3	5
2. I avoided letting myself get upset when I thought about it or was reminded of it.	0	1	3	5
3. I tried to remove it from memory.	0	1	3	5
4. I had trouble falling asleep or staying asleep because of thoughts about it that came into my mind.	0	1	3	5
5. I had waves of strong feelings about it.	0	1	3	5
6. I had dreams about it.	0	1	3	5
7. I stayed away from reminders of it.	0	1	3	5
8. I felt as if it hadn't happened or wasn't real.	0	1	3	5
9. I tried not to talk about it.	0	1	3	5
10. Pictures about it popped into my head.	0	1	3	5
11. Other things kept making me think about it.	0	1	3	5
12. I tried not to think about it.	0	1	3	5
13. I was aware that I still had a lot of feelings about it, but I didn't deal with them.	0	1	3	5
14. Any reminder brought back feelings about it.	0	1	3	5
15. My feelings about it were kind of numb.	0	1	3	5

Impact of Event Scale From Horowitz, Alvarez, Wilner, 1979 and Horowitz, 2004
http://www.mardihorowitz.com/impact_of_events_scale

Semi Structured Interview Schedule

Interview Prompts

1. Did you use the family guide to think about decisions regarding the care of your family member in ICU? Yes No (if no, Skip to 3).
2. How did you use the guide?
 - How often?
 - Did you need help to complete it?
 - Who helped you complete the guide?
 - Did you use it more than once?
 - Did you use it to prepare for meetings between healthcare team and family members?
3. Was the timing of decision support acceptable?
 - Would you have like to receive the guide earlier?
 - Or later in your hospital stay?
4. What were the advantages (or disadvantages) of getting information about decision making?
5. Did you have any difficulty completing the questionnaires? If yes, which ones?

Family Meeting Observation Tool

Use of Decision Guide (Check box if YES, element was discussed)

Options

- Life support
- Comfort care
- Other

Situation before ICU

- Health problem
- Prior functional status (PPS)
- Prior quality of life (Missoula-VITAS Quality of Life Index)

Situation right now

- Organ system failure
- Types of life support considered reasonable for this patient

Patient values

- Advanced directive or other document
- Discuss how to consider ACP documents in the decision making process
- Patient values for options
- Family values for options
- Healthcare team values for options

Others

- Identify other family members/healthcare team members involved
- Discuss other perspectives affect decision making about level of care
- Discuss preferred role in decision-making
- Discuss preferred choice

Evaluate progress in decision making

- Feeling informed
- Uncertainty
- Clear values
- Support needs
- Quality of decision
- Next steps
- Time to revisit decision

Third Observer OPTION tool

(Healthcare Professional) Time 1 Questionnaire (Enrolment)

Please answer these questions about yourself.

1. What is your relationship to the patient?
 Healthcare provider Spouse Partner Child Parent Sibling
 Friend Other, specify _____
2. Are you the legal surrogate decision-maker for this patient? Yes No Unsure
3. How old are you? ____years.
4. Sex male female
5. What is your marital status? never married married widowed divorced
 Other _____
6. What is your highest level of education?
 Elementary Some high school High School
 College University Masters PhD
7. What is your occupation or profession? _____
8. How long have you worked in the ICU setting? ____years

How do you prefer to be involved in decision making?

This tool asks about roles deciding about type of care. Answer from *your point of view* by putting a tick in one box only.

- I prefer that family make the decision about which type of care the patient will receive.
- I prefer that family make the final decision about the patient's type of care after seriously considering the doctor's opinion.
- I prefer that the doctor and family share responsibility for deciding which type of care is best for the patient.
- I prefer that the doctor makes the final decision about which type of care will be used but seriously considers the family's opinion.
- I prefer to leave all decision regarding the patient's type of care to the doctor.

How prepared do you feel to participate in decision making?

The following questions are about the support provided to family member(s) as they participate in decisions about the type of care for the patient in ICU. Type of care decisions include decisions to use life support, or decisions to withhold or withdraw life support and focus on comfort care. Circle the number that shows how much you agree with each statement.

Did the support provided:	Not at all	A little	Some- what	Quite a bit	A great deal
1. help family fully understand the risks and benefits of each option?	1	2	3	4	5
2. help family identify the importance that the patient would place on the risks and benefits of each option?	1	2	3	4	5
3. prepare family for discussions during meetings with members of the ICU healthcare team?	1	2	3	4	5
4. help family be as involved in the decision making process as they desired?	1	2	3	4	5
5. help family to make a more informed decision?	1	2	3	4	5
Did the support provided:	Not at all	A little	Some- what	Quite a bit	A great deal
6. help you more fully understand the issues that are most important to the patient?	1	2	3	4	5
7. help you tailor your counselling to their preference for decision participation?	1	2	3	4	5
8. facilitate your discussions with family members?	1	2	3	4	5
9. improve the way your time was spent in discussion with family members?	1	2	3	4	5
5. improve the quality of your discussions with family members?	1	2	3	4	5

©Preparation for Decision Making Scale (Graham, O'Connor 1996, revised 2005) University of Ottawa

How much are you involved in decision making about type of care for the patient in ICU?

Please answer every question from <i>your point of view</i> by putting a tick in one box only for each question.				
1. A health problem was identified, where it was made clear that a decision was needed.	Strongly Agree	Agree	Disagree	Strongly Disagree
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. More than one way to manage the health problem was described.	Strongly Agree	Agree	Disagree	Strongly Disagree
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Different sources of information (e.g. leaflets, websites, contact with other people) to help make the decision were offered.	Strongly Agree	Agree	Disagree	Strongly Disagree
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Different options (including the possibility of doing nothing) were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. The advantages, disadvantages and possible outcomes of options were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Ideas or expectations about managing the health problem were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Concerns or worries about managing the health problem were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. It was made sure that information had been understood.	Strongly Agree	Agree	Disagree	Strongly Disagree
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. There were opportunities to ask questions.	Strongly Agree	Agree	Disagree	Strongly Disagree
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. The preference to take part in the decision (or not) was respected.	Strongly Agree	Agree	Disagree	Strongly Disagree
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. During the consultation, a decision was made; or there was an agreement to postpone making the decision.	Strongly Agree	Agree	Disagree	Strongly Disagree
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. The possibility of coming back to the decision was discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

dyadic OPTION 2008 For further information contact Professor Glyn Elwyn.

(Healthcare Professional) Time 2 Questionnaire

What did you think about the guide called *Planning care for critically ill patients in the Intensive Care Unit?*

Please check one answer for each question.

1. Did you read the entire guide?

- Yes
- No

2. Did anyone else (such as a member of the healthcare team) help family members complete the guide?

- Yes Who: _____
- No

3. How would you rate the amount of information in the guide?

- Much less than family members needed
- A little less than family members needed
- About the right amount
- A little more than family members needed
- A lot more than family members needed

4. How balanced was the guide's information about type of care in ICU?

- Clearly slanted towards **life support treatments (such as a breathing machine)**
- A little slanted towards **life support treatments**
- Completely balanced
- A little slanted towards **comfort care (or treatments that focus on relieving pain and other problems)**
- Clearly slanted towards **comfort care**

5. How clear was the information in the guide?

- Everything was clear
- Most things were clear
- Some things were clear
- Many things were unclear

6. How helpful is the guide in helping family members make decisions about treatment options?

- Very helpful
- Somewhat helpful
- A little helpful
- Not helpful

7. Would you recommend this guide to other family members who are considering care options for a patient with critical illness?

- I would definitely recommend it
- I would probably recommend it
- I would probably not recommend it
- I would definitely not recommend

8. Overall, how would you rate the guide?

- Poor
- Fair
- Good
- Very good
- Excellent

What did you think about the summary report for the healthcare team?

Please check one answer for each question.

9. Did you use the summary report?

- Yes
- No

10. Did anyone else review the summary report?

- Yes Who: _____
- No

11. How would you rate the amount of information in the summary report?

- Much less than the healthcare team needed
- A little less than the healthcare team needed
- About the right amount

- A little more than the healthcare team needed
- A lot more than the healthcare team needed

12. How clear was the information in the summary report?

- Everything was clear
- Most things were clear
- Some things were clear
- Many things were unclear

13. Overall, how would you rate the summary report?

- Poor
- Fair
- Good
- Very good
- Excellent

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How prepared do you feel to participate in decision making?

The following questions are about the support provided to family member(s) as they participate in decisions about the type of care for the patient in ICU. Type of care decisions include decisions to use life support, or decisions to withhold or withdraw life support and focus on comfort care. Circle the number that shows how much you agree with each statement.

Did the support provided:	Not at all	A little	Some-what	Quite a bit	A great deal
1. help family fully understand the risks and benefits of each option?	1	2	3	4	5
2. help family identify the importance that the patient would place on the risks and benefits of each option?	1	2	3	4	5
3. prepare family for discussions during meetings with members of the ICU healthcare team?	1	2	3	4	5
4. help family be as involved in the decision making process as they desired?	1	2	3	4	5
5. help family to make a more informed decision?	1	2	3	4	5
Did the support provided:	Not at all	A little	Some-what	Quite a bit	A great deal
6. help you more fully understand the issues that are most important to the patient?	1	2	3	4	5
7. help you tailor your counselling to their preference for decision participation?	1	2	3	4	5
8. facilitate your discussions with family members?	1	2	3	4	5
9. improve the way your time was spent in discussion with family members?	1	2	3	4	5
5. improve the quality of your discussions with family members?	1	2	3	4	5

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How much are you involved in decision making about type of care for the patient in ICU?

Please answer every question from *your point of view* by putting a tick in one box only for each question.

1. A health problem was identified, where it was made clear that a decision was needed.	Strongly Agree	Agree	Disagree	Strongly Disagree
2. More than one way to manage the health problem was described.	Strongly Agree	Agree	Disagree	Strongly Disagree
3. Different sources of information (e.g. leaflets, websites, contact with other people) to help make the decision were offered.	Strongly Agree	Agree	Disagree	Strongly Disagree
4. Different options (including the possibility of doing nothing) were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
5. The advantages, disadvantages and possible outcomes of options were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
6. Ideas or expectations about managing the health problem were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
7. Concerns or worries about managing the health problem were discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree
8. It was made sure that information had been understood.	Strongly Agree	Agree	Disagree	Strongly Disagree
9. There were opportunities to ask questions.	Strongly Agree	Agree	Disagree	Strongly Disagree
10. The preference to take part in the decision (or not) was respected.	Strongly Agree	Agree	Disagree	Strongly Disagree
11. During the consultation, a decision was made; or there was an agreement to postpone making the decision.	Strongly Agree	Agree	Disagree	Strongly Disagree
12. The possibility of coming back to the decision was discussed.	Strongly Agree	Agree	Disagree	Strongly Disagree

dyadic OPTION 2008 For further information contact Professor Glyn Elwyn.

Semi Structured Interview Schedule

Interview Prompts

1. Did you use the summary report or information you learned while coaching families to think about the family's involvement in decisions regarding the patient's care in ICU?

Yes No (if no, Skip to 3).

2. How did you use the Guide / DSR?

How often?

Did you ask questions to clarify answers given to the guide?

Did you help family members complete the guide? More than once?

Did you use it to prepare for meetings or conversations with family members?

Who did you share information from the guide / DSR with?

3. Was the timing of decision support acceptable?

Would you have like use the guide with families earlier?

Or later in their hospital stay?

4. What were the advantages (or disadvantages) of getting information about decision making?

5. Did you have any difficulty completing the questionnaires? If yes, which ones?

